ABSTRACT

Effects of a High Protein Diet on Weight Loss, Markers of Health, and Functional Capacity in Senior-Aged Females Participating in the Curves® Fitness Program

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Purpose: To determine the effectiveness of elderly females aged 60-75 years following the Curves fitness and weight loss program on body composition, markers of health, and functional capacity. Methods: 55 senior aged overweight females (66 ± 5 years; 79 ± 11 kg) were randomly assigned to one of three groups: High Protein diet + Exercise (HP); High Carbohydrate diet + Exercise (NCHO); or Exercise only (E). Participants were instructed to follow their respective nutrition plans and complete a supervised 30 minute Curves circuit resistance-training program three times a week. The participants underwent an array of tests at 0, 10 and 14 weeks. An analysis of variance (ANOVA) for repeated measures was used to analyze the data. Results: Subjects in the HP experiencing significantly greater weight loss (HP -4.8 ± 3.2%, NCHO -3.0 ± 2.9%, E -1.1 ± 2.3%, p=0.001), fat mass (HP -10.2 ± 5.9%, NCHO -5.7 ± 4.0% and E -2.7 ± 3.9%, p=0.001), and percent body fat (HP -6.3 ± 3.5%, NCHO -3.8 ± 3.4%, and E only -2.2 ± 3.6%). Improvements were also noted in an appetite regulating hormones leptin (HP -42.1 ± 21.3%, NCHO 43.4 ± 56.1% and E .80 ± 35.1%, p=0.000). No significant

changes were observed in fat free mass or resting energy expenditure. All groups experienced improvements in strength, muscular endurance, aerobic capacity, and a number of markers of health.

Summary: The Curves exercise and weight loss program is effective in senior aged females in promoting weight loss and favorable body composition changes. The greatest effects were seen in the HP group.

Effects of a High Protein Diet on Weight Loss, Markers of Health, and Functional Capacity in Senior-Aged Females Participating in the Curves® Fitness Program

by

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A Dissertation

Approved by the Department of Health, Human Performance and Recreation

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DEDICATION

To

My family

CHAPTER ONE

Introduction and Rationale

Background

Obesity is a problem that complicates and exacerbates the aging process. The rising incidence of obesity in the older population has brought about intense concern in the medical community. The segment of elderly over age 65 is predicted to continue to be the fastest growing segment of the United States population. The number of obese older persons has increased due to the increase in the total number as well as the percentage of obese older citizens. In 1991, 14.7% of persons in the United States aged 60-79 years old and 11.4% of those above age 70 were obese (Mokdad et al., 1999).

Aging women in the United States have been shown to be less active, more likely to suffer from falls and are more expensive in health care expenditures (U.S. Department of Health and Human Services, 2000). The adverse effects of obesity include mortality and a myriad of medical co-morbid conditions. These medical problems include: metabolic abnormalities, arthritis, pulmonary abnormalities, urinary incontinence, cataracts and certain types of cancer (Layman et al., 2005). Another major concern in the elderly is sarcopenia. The loss of muscle mass not only impacts metabolic disorders (i.e., insulin resistance) but significantly affects functional capacity. The beneficial effects of exercise have the ability to offset mortality rates and can have a positive effect on body composition if done correctly (Chernoff, 2006).

Exercise plays a critical role in weight loss, metabolism, functional capacity and weight maintenance. The current authorities on exercise prescription include the Center for Disease Control (CDC) and the American College of Sports Medicine (ACSM). Both of these organizations have summarized the extensive research on successful weight loss strategies in the elderly in order to develop current exercise guidelines (Mazzeo & Tanaka, 2001). Their recommendations include regular activity that utilizes large muscle groups, rhythmic, aerobic forms of exercise and resistance training. ACSM and the CDC distinguish levels of cardiovascular intensity by outcome goals. A program consisting of light-moderate activity optimizes health (Mazzeo & Tanaka, 2001). The Curves circuit has the capacity to meet all of these criteria. The Curves circuit includes thirteen bidirectional hydraulic exercise machines that trains all major muscle groups interspersed with eight stations that are utilized for aerobic activity such as callisthenic exercises. The Curves program meets the criteria summarized by the CDC and ACSM in combining aerobic and resistance training utilizing large muscle groups and has the capacity to meet requirements for moderate to high intensity exercise. This is accomplished by increasing the speed and number of repetitions performed on each unit by the user.

To date Curves research has yet to investigate the applicability of the Curves program to older females aged 70 and above. The older female population is in need of a non-intimidating exercise program that would allow safe and effective gains in overall fitness. The Curves hydraulic circuit can provide an excellent work out for this population that is effort dependent and offered in a safe and monitored environment. Previous research utilizing the Curves program, has shown that muscle strength and endurance improved by 10-15% during the fourteen week intervention on a female

populations aged 25-65. Participant testing also showed a 10% increase in maximal aerobic capacity (Kreider, 2005). Previous Curves intervention studies have also shown improvements in weight loss while maintaining muscle mass, improving cardiovascular health and overall well being/quality of life (Kreider, 2005).

Many studies have shown that resistance training can reverse sarcopenia (Evans, 2002; Porter, Vandervoort & Lexell, 1995) and is the best mode of exercise for this condition. The majority of research in this population has primarily been with exercise equipment that intended for isotonic exercise. There is a need for additional research with hydraulic equipment utilizing moderate intensity exercise. Willoughby & Pelsue (1998) showed that gains can be made in comparing moderate intensity exercise and high intensity exercise. In a 12 week study done with elderly males, they compared moderate intensity isotonic exercise to high intensity isotonic exercise; they found both interventions increased muscle strength as well as Type I Myosin Heavy Chain mRNA isoforms. Not only does resistance training impede the rate of sarcopenia, but it also substantially improves physical function. Researchers reported an increase in mid thigh cross-sectional area by approximately 12% with strength improvements of twofold in older men after a 12 week high intensity isotonic resistance training program (Frontera, Meredith, O'Reilly, Knutgen & Evans, 1988). It appears that the frail also benefit from resistance training. Yarasheski et al. (1999) conducted a study to determine if weight-lifting exercise increases the rate of muscle protein synthesis in physically frail 76- to 92-year old women and men. Each participant enrolled in a 3 month physical therapy program that was followed by 3 months of supervised weight-lifting exercise for 3 days per week. The authors concluded that muscle contractile protein synthetic pathways in

physically frail 76- to 92-yr-old women and men respond and adapt to the increased contractile activity associated with progressive isotonic resistance training. Studies that used hydraulic equipment in the aging population have also shown gains in strength as well as cardiovascular markers. Haennel, Quinney & Kappagoda (1991) looked at the effects of hydraulic circuit training on stroke volume, cardiac output, aerobic peak VO2 and muscular strength and endurance in 24 post-coronary artery bypass patients (mean age= 52.8 ± 2.6 years). There were two intervention groups and one control group. The intervention groups were randomized into eight weeks of cycle training or hydraulic circuit training and were compared to a non-exercising control group. Post training, both intervention groups showed improvements in peak VO_2 with increases in stroke volume and Qc and a reduction in heart rate. The HCT group showed gains in both muscular strength and endurance. This study showed that Hydraulic resistance training can elicit improvements in cardiovascular fitness and muscular strength endurance. Based on these studies it appears that resistance training should be recommended to prevent and reverse sarcopenia. Studies have demonstrated that total muscle cross-sectional area decreases by approximately 40% during the ages of 20 and 60 (Doherty, 2003). The loss of muscle mass is also associated with a decline in function. Decreased functional capacity leads to disability which in turn worsens conditions associated with obesity such as diabetes, arthritis, hypertension and sleep disturbances.

The main focus of this study will be to investigate which of the current Curves dietary regimens, the high protein diet (HP) and/or the normal carbohydrate diet (NCHO) produce favorable results in the areas of weight loss and muscle mass retention in an elderly female population. There is currently a paucity of research in determining the

ideal macronutrient and caloric content for this population. There have been few published studies on dietary weight loss intervention specifically in older subjects (Bray & Bouchard, 2004). However, there is a plethora of research in the frail and diseased elderly with diet manipulation but these studies focus on specific pathological disorders such as anemia, bone mass and wasting in chronic illness. Furthermore, current research featuring participants above age 60 is primarily in acute care settings or an institutionalized setting (i.e., nursing home). In these populations HP diets have been suggested in diseased states in order to enhance muscle mass and/or offset it's decline. Other health benefits of HP diets are suggested in the areas of promoting bone mass retention (Devine et al., 2005) enhanced insulin sensitivity and lowering triglyceride levels (Foster et al., 2003). HP diets also contribute a positive impact on metabolic processes as well. HP diets have been shown to produce more favorable results in enhancing insulin sensitivity, reducing central adiposity and improving risk factors for diabetes and heart disease (Noakes, Keogh, Foster & Clifton, 2005). The Curves® nutrition program offers higher protein content at 55% than macronutrient percentages previously cited at 30%. Higher protein diets have been shown to aide in retaining muscle mass during weight loss due to enhanced protein synthesis (Baba, et al., 1999; Piatti, et al., 1994). However, it is currently unknown what the ideal amount of protein is required for this population in order to sustain and promote muscle mass (Layman et al., 2005). The Exercise and Sports Nutrition Laboratory (ESNL) at Baylor University has been conducting extensive studies on the efficacy of the Curves program. Kreider et al. (2005) has performed extensive research on the Curves fitness and diet program. The research findings demonstrated that women (aged 25-65) following this program for 14

weeks lost 10-14 pounds, increased resting energy expenditure by 100-400 kcal/day, and had a reduction in waist & hip measurements of 1.5-2 inches. Maximal aerobic capacity increased by 10% and muscular strength/endurance improved by 10-15%. While total cholesterol decreased by 4%, LDL decreased by 3%, triglycerides decreased by 12%, and leptin was reduced overall by 17%. In addition, fasting insulin was reduced by 15% overall, while insulin sensitivity improved by 19%. Body image, self-esteem, and quality of life increased among the participants. Women new to exercise can burn approximately 164-238 kcals during a 30-minute Curves workout. In addition, the strength training components of the program indicated a 50-75% of 1RM with an average of 15-20 repetitions performed per 30-second time frame (Campbell, et al., 2005). As a result, the research has shown that the Curves program is highly effective in promoting weight loss, improving markers of health and enhancing fitness. Theoretically, the Curves program may be efficacious for elderly females in that it promotes improvements in strength and weight loss.

The Curves program offers an organized, pre-calculated nutritional program that when coupled with exercise has been shown to be quite effective in younger age groups. The results of this study will provide much needed data in determining the ideal nutritional regimen for the elderly in the areas of body composition, specifically weight loss and muscle mass and how these changes may affect functional capacity.

Statement of the Problem

Do high protein diets promote improvement in the areas of body composition, markers of health, and functional capacity in senior-aged women participating in the

Curves fitness program compared to a normal carbohydrate diet or Curves exercise only intervention?

Purpose of the Study

To determine the effects of the Curves protocol high protein diet in elderly females aged 60-75 years in the areas of body composition, markers of health, and functional capacity.

General Study Overview

This study will be conducted in a randomized manner for senior females, age 60-75 years old. Participants meeting physician approved criteria, will be randomly assigned to an exercise-only, an exercise and normal carbohydrate group (NCHO), or an exercise and high protein (HP) group. The independent variables are the type of Curves diet regimens (NCHO or HP) and the exercise only group. The dependent variables include: body composition (weight, FM, FFM, %body fat); total body water assessment; anthropometric measures, muscular strength, functional capacity, maximal cardiopulmonary exercise capacity and functional cardiopulmonary capacity, standardized quality of life (SF-36), eating satisfaction and leptin, ghrelin, adiponectin, insulin, and ketones. Fasting general medical blood profiles (whole blood immune function analysis, a general clinical chemistry panel will also be drawn. Statistical analysis will be performed on fasting glucose levels and lipid values only. The remaining general chemistry panel and whole blood immune function analysis will be monitored for safety reasons only.

Hypotheses

Based on the volume of published research studies aforementioned and the variables denoted above, the following hypotheses will be evaluated:

H_1- There will be statistically significant reductions in weight, FM, FFM, and percent body fat in the high protein group versus the normal carbohydrate group.

H_2- There will be statistically significant reductions in the waist to hip ratio in the high protein group as compared to the normal carbohydrate group.

H_3- There will be statistically significant reductions in glucose variables (e.g., fasting glucose and insulin) in the diet groups as compared to the exercise only groups.

H_4- There will be statistically significant improvements in hormonal levels among all three groups.

H_5- There will be statistically significant reductions in lipid variables among diet groups as compared to the exercise only group.

H_6- There will be statistically significant reductions in resting cardiovascular parameters including resting heart rate and blood pressure in all three groups.

H_7- There will be statistically significant increases in body strength among all three groups.

H_8- There will be statistically significant improvements in functional capacity in both diet groups on the four tests of balance.

H_9- There will be statistically significant improvement in psychological status as measured via questionnaires among all three groups. Specifically, it is predicted that participants in all groups will demonstrate increased physical function and vitality and decreased physical pain, increased vigor scores and decreased depression.

Previous research does not inform or demonstrate the nature of the following effects/relationships. However, it is important to examine these relationships to check manipulations or confirm the lack of relationship. Therefore, only the null hypothesis is stated in the following cases:

Null Hypotheses

H01- There will be no statistically significant differences in HDL values between groups.

H02- There will be no statistically significant differences in HDL values over time.

H03- There will be no statistically significant changes in standard clinical chemistries assessing general health status

H04-There will be no statistically significant time effect for resting energy expenditure in all three groups.

H05- There will be no statistically significant differences in between group effects on the four tests of balance.

Delimitations

The research study followed the guidelines listed below:

1. There will be 60 sedentary overweight, senior aged female participants (BMI > 27) between the ages of 60-75 that will participate in the study. The participants will be medically cleared by a physician.

2. Participants will be recruited with flyers posted on campus, physician offices/clinics, and retirement facilities. Advertisements were run in the local newspapers.

3. Familiarizations and testing sessions will be conducted in the Exercise and Sport Nutrition Laboratory (ESNL) at Baylor University.

4. Participants will be randomly assigned to one of three treatment groups.

5. Participants followed exercise prescription guidelines in a supervised Curves 30-minute fitness program three times per week throughout the investigation.

Limitations

1. Participants will be sedentary and overweight females (BMI > 27) between the ages of 60-75, meet medical clearance qualifying criteria and able to seek physician approval.

2. Participants will be required to adhere to the Curves 30-minute fitness program three times per week throughout the investigation.

3. Participants will be required to follow the Curves International weight loss program within a free-living environment.

4. Participants will be required to adhere to honesty in completing forms and questionnaires and follow the prescribed regimens to the best of their ability.

5. Participants will complete the Eating Satisfaction Survey which has not been proven valid or reliable.

Assumptions

1. Participants will follow the Curves weight loss program as specified by the assigned diet regimen.

2. Participants will adhere to verbal and written instructions, on more than one occasion to refrain from exercise for 48 hours prior to baseline testing.

3. Participants will fast for 10-12 hours prior to lab collection.

4. Participants will follow the intensity guidelines for all work outs per instructions.

Terms and Definitions

1. Adiponectin (Acrp30, apM1) - a protein hormone that modulates a number of metabolic processes, including glucose regulation and fatty acid catabolism. This hormone is exclusively secreted from adipose tissue into the bloodstream and is very abundant in plasma relative to many hormones. Levels of the hormone are inversely correlated with body mass index (BMI). The hormone plays a role in the suppression of the metabolic derangements that may result in type 2 diabetes, obesity, atherosclerosis and non-alcoholic fatty liver disease (NAFLD) (www.medterms.com)

2. Adiposity- "Adipose" literally means "fat". A term usually used to refer specifically to tissue made up of primarily fat cells such as the yellow layer of fat beneath the skin. The word "adipose" comes from the Latin "adeps" meaning "fat, particularly lard." (www.medterms.com).

3. Anthropometry- the study of human body measurement for use in anthropological classification and comparison (www.medterms.com).

4. Anthropometric measures- measures of or relating to anthropometry (www.medterms.com).

5. Afterload- the pressure that the chamber of the heart has to generate in order to eject blood out of the chamber (www.medterms.com).

6. β-Hydroxybutyrate - acetoacetate and acetone are collectively called ketone bodies (www.medterms.com).

7. Bioelectrical Impedance Analysis (BIA) - Body Water Assessment - Procedure used to estimate total body water and body fat percentage by measuring bio-resistance of water and body tissues based on a minute low energy, high frequency current (500 micro-amps at a frequency of 50 kHz) transmitted through the body (McArdle, Katch & Katch, 2000).

8. Body Composition - Test used to determine body fat percentage (www.medterms.com).

9. Body Mass Index (BMI) - statistical measure of the weight of a person scaled according to height defined as kilograms per meter squared (www.medterms.com).

10. Cancer- any malignant growth or tumor caused by abnormal and uncontrolled cell division; it may spread to other parts of the body through the lymphatic system or the blood stream (www.medterms.com).

11. Cardiac Output (CO) - the volume of blood being pumped by the heart, in particular a ventricle in a minute. It is equal to the heart rate multiplied by the stroke volume (www.medterms.com).

12. Complete Blood Count (CBC) - A complete blood count (CBC) test measures the following: number of red blood cells (RBCs), number of white blood cells (WBCs), total amount of hemoglobin in the blood, the fraction of the blood composed of red blood cells (hematocrit), the mean corpuscular volume (MCV) -- the size of the red blood cells, and includes information about the red blood cells that is calculated from the other measurements (mean corpuscular hemoglobin(MCH) and mean corpuscular hemoglobin concentration (MCHC) and the platelet count (www.medterms.com).

13. Co-morbid- The presence of one or more disorders (or diseases) in addition to a primary disease or disorder; or the effect of such additional disorders or diseases (www.medterms.com).

14. Cortisol - Hormone produced by the body to fight stress and serve as an anti-inflammatory helper (www.medterms.com).

15. Diabetes Mellitus (DM) - a metabolic disorder characterized by hyperglycemia (high glucose), Diabetes is due to one of two mechanisms: Inadequate production of insulin or inadequate sensitivity of cells to the action of insulin (www.medterms.com).

16. Food Record - Form used by participants to record all fluid and food intake three days during one week and one weekend day for the length of the study in order to standardize nutritional intake (www.answers.com).

17. Diastolic blood pressure- the lowest pressure (at the resting phase of the cardiac cycle) (www.medterms.com).

18. Dual-Energy X-Ray Absorptiometry (DEXA) - Procedure used for limited x-ray technology to determine body composition and bone mineral density (McArdle, Katch & Katch, 2000).

19. Eating Satisfaction Survey - Questionnaire used to determine eating satisfaction of assigned diet (Heavin, 2003).

20. End Diastolic Volume (EDV) - volume of blood in the ventricle at the end of filling (McArdle, Katch & Katch, 2000).

21. End Systolic Volume (ESV) - volume of blood in the ventricles just after systole (McArdle, Katch & Katch, 2000).

22. Elderly- of or pertaining to persons in later life (www.medterms.com).

23. Ejection Fraction (EF) - the fraction of end diastolic volume that is ejected with each beat (McArdle, Katch & Katch, 2000).

24. Fat Mass (FM) - Term used to describe the fat weight of the human body (McArdle, Katch & Katch, 2000).

25. Gerontology- the study of aging. It is to be distinguished from geriatrics, which is the study of the diseases of the aging (www.medterms.com).

26. Ghrelin- a hormone produced by P/D1 cells lining the fundus of the human stomach that stimulate appetite. In rodents, X/A-like cells produce ghrelin. Ghrelin levels increase before meals and decrease after meals. It is considered the counterpart of the hormone leptin, produced by adipose tissue, which induces satiation when present at higher levels. Ghrelin also stimulates the secretion of growth hormone from the anterior pituitary gland (www.medterms.com).

27. Heart Disease- umbrella term for a number of diseases affecting the heart (McArdle, Katch & Katch, 2000).

28. Hyperlipidemia- presence of abnormal or elevated levels of lipids (www.medterms.com).

29. Insulin- polypeptide hormone that regulates carbohydrate metabolism (www.medterms.com).

30. Insulin sensitivity- Insulin resistance (IR) is a condition in which the cells of the body become resistant to the effects of insulin, that is, the normal response to a given amount of insulin is reduced. As a result, higher levels of insulin are needed in order for insulin to have its effects (www.medterms.com).

31. Isotonic strength- These terms combine the prefix “iso” (meaning “same”) and metric” (distance). In “isotonic exercises the force applied to the muscle does not change (while the length of the muscle decreases or increases) while in “isometric” exercises the length of the muscle does not change (McArdle, Katch & Katch, 2000).

32. Lean Body Mass (LBM) - Term used to describe the weight of the human body excluding the fat mass (McArdle, Katch & Katch, 2000).

33. Leptin- a 16 kDa protein hormone that plays a key role in regulating energy intake and energy expenditure, including the regulation of appetite and metabolism (www.medterms.com).

34. Lipid - any oily organic compound insoluble in water but soluble in organic solvents; essential structural component of living cells (along with proteins and carbohydrates) (www.medterms.com).

35. Limits of Stability Directional Control (LOSDCLC)- A comparison of the amount of movement in the intended direction (towards the target) to the amount of extraneous movement (away from the target) (http://www.onbalance.com/).

36. Limits of Stability Endpoint excursion (LOSEPEC) - The distance of the first movement towards the designated target, expressed as a percentage of maximum LOS distance. The endpoint is considered to be the point at which the initial movement towards the target ceases (http://www.onbalance.com/).

37. Limits of Stability Maximum Excursion (LOSMXEC) - The maximum distance achieved during the first trial (http://www.onbalance.com/).

38. Limits of Stability Movement Velocity (LOSMVLC) - The average speed of Center of Gravity (COG) movement in degrees per second (http://www.onbalance.com/).

39. Limits of Stability Reaction Time (LOSRTC) - The time in seconds between the command to move and the patient's first movement (http://www.onbalance.com/).

40. Macronutrients- either a carbohydrate, protein, or fat (McArdle, Katch & Katch, 2000).

41. Maximal Cardiopulmonary Exercise Capacity- Procedure used to determine maximal aerobic capacity and anaerobic threshold to evaluate the effects of exercise training on fitness and exercise capacity (McArdle, Katch & Katch, 2000).

42. Modified Bruce Protocol- A standardized multistage treadmill test for assessing cardiovascular health that is an alteration in the Bruce protocol so that the treadmill is initially horizontal rather than uphill, with the first few intervals increasing the treadmill slope only (McArdle, Katch & Katch, 2000).

43. Morbidity- the state of being diseased (www.medterms.com).

44. Mortality- the quality or state of being mortal; the ratio of deaths in an area to the population of that area; expressed per 1000 per year (www.medterms.com).

45. NeuroCom Smart Equitest- Balance Tests - Testing procedures used to collect data on postural balance and mobility utilizing the following tests in order: Sit to Stand (STS),

Forward Step Up and Over (SUO), Limits of Stability (LOS), Sensory Organization Test (SOT) (http://www.onbalance.com/).

46. Osteoarthritis (OA) - chronic breakdown of cartilage in the joints; the most common form of arthritis occurring usually after middle age (www.medterms.com).

47. Osteoporosis - abnormal loss of bony tissue resulting in fragile porous bones attributable to a lack of calcium; most common in postmenopausal women (www.medterms.com).

48. Psychometric Assessments - Questionnaires completed by participants to determine the eating satisfaction and quality of life throughout the length of the study (Fontaine, Cheskin & Barofsky, 1996).

49. Sit to Stand Cog Sway Velocity (STSCSVM) - Documents control of the COG over the base of support during the rising phase and for 5 seconds thereafter. Sway is expressed in degrees per second (http://www.onbalance.com).

50. Sit to Stand Left/Right Weight Symmetry (STSACXM) - Documents differences in the percentage of body weight borne by each leg during the active rising phase (http://www.onbalance.com/).

51. Sit to Stand Rising Index (STSRIM) - The amount of force exerted by the legs during the rising phase. The force is expressed as a percentage of the patient's body weight (http://www.onbalance.com/).

52. Sit to Stand Weight Transfer (STSWTRM) - The time in seconds required to voluntarily shift COG forward beginning in the seated position and ending with full weight bearing on the feet (http://www.onbalance.com/).

53. Step Up and Over Lift Impact Index (Left) (SUOIILM) - Quantifies the maximum vertical impact force as the lagging leg lands on the surface, expressed as a percentage of body weight (http://www.onbalance.com/).

54. Step Up and Over Lift Impact Index (Right) (SUOIIRM) - Quantifies the maximum vertical impact force as the lagging leg lands on the surface, expressed as a percentage of body weight (http://www.onbalance.com/).

55. Step Up and Over Lift-Up Index (SUOLUIL) - Quantifies the maximum lifting (concentric) force exerted by the leading leg and is expressed as a percentage of the individual's weight. (http://www.onbalance.com/).

56. Sarcopenic Obesity - the combination of obesity and loss of muscle mass (www.medterms.com).

57. Senior- of, for, or pertaining to a senior citizen or senior citizens as a group (www.medterms.com).

58. Six Minute Walk Test (SMWT or 6MWT) - the distance walked in a six minute time frame that indirectly assesses cardiopulmonary capacity (Bautmans, Lambert & Mets, 2004).

59. Step Up and Over Lift-Up Index (SUOLUIL) - Quantifies the maximum lifting (concentric) force exerted by the leading leg and is expressed as a percentage of the individual's weight (http://www.onbalance.com/).

60. Step Up and Over Lift (leading leg) (SOULUIR) - Quantifies the maximum lifting (concentric) force exerted by the leading leg and is expressed as a percentage of the individual's weight (http://www.onbalance.com/).

61. Step Up and Over Movement Time (left leg) (SOUMTLM)- Quantifies the number of seconds required to complete the maneuver, beginning with the initial weight shift to the non-stepping (lagging) leg and ending with the impact of the lagging leg onto the surface (http://www.onbalance.com/).

62. Step Up and Over Lift (right leg) (SOUMTRM)- Quantifies the number of seconds required to complete the maneuver, beginning with the initial weight shift to the non-stepping (lagging) leg and ending with the impact of the lagging leg onto the surface (http://www.onbalance.com/).

63. Step Up and Over Movement Time (SOUMTM) - Quantifies the number of seconds required to complete the maneuver, beginning with the initial weight shift to the non-stepping (lagging) leg and ending with the impact of the lagging leg onto the surface (http://www.onbalance.com/).

64. Step Up and Over Lift Impact Index (left) (SUOIILM) - Quantifies the maximum vertical impact force as the lagging leg lands on the surface, expressed as a percentage of body weight (http://www.onbalance.com/).

65. Step Up and Over Lift (Right) (SUOIIRM) - Quantifies the maximum vertical impact force as the lagging leg lands on the surface, expressed as a percentage of body weight (http://www.onbalance.com/).

66. Stroke - a sudden loss of consciousness resulting when the rupture or occlusion of a blood vessel leads to oxygen lack in the brain (syn: apoplexy, cerebrovascular accident, CVA) (www.medterms.com).

67. Triacylglycerol- a glyceride in which the glycerol in esterified with three fatty acids (www.medterms.com).

68. Total Body Water (TBW) - The sum of intracellular water and extracellular water (volume), about 60% of total body weight (McCardle, Katch & Katch, 2000).

69. Total Composite Equilibrium Score (SOTCOMP) - The score that quantifies the Center of Gravity (COG) sway or postural stability under each of the three trials of the six sensory conditions. Effective use of individual sensory inputs is determined from the overall pattern of scores on the six conditions. The composite equilibrium score, the weighted average of the scores of all sensory conditions, characterizes the overall level of performance (http://www.onbalance.com/).

70. Vital Capacity (VC) - the maximum amount of air that can be exhaled after a maximum inhalation (usually tested with a spirometer); used to determine the condition of lung tissue (McCardle, Katch & Katch, 2000).

71. Quality of Life (QOL/SF-36) - Questionnaire used to measure health-related quality of life by assessing eight different dimensions: physical functioning, role limitations caused by physical health problems, bodily pain, general health perceptions, energy/fatigue, social function, role limitation caused by emotional problems, and emotional well-being (Fontaine, Cheskin & Barofsky, 1996).

72. Waist to Hip Ratio (WHR) - waist circumference divided by hip circumference (McCardle, Katch & Katch, 2000).

73. White Blood Cells (WBC) - Cells responsible for responding to cellular injury and engulfing bacteria. There are five types of white blood cells: neutrophils, basophils, eosiniphils, lymphocytes, and monocytes (www.medterms.com).

CHAPTER TWO

Literature Review

Prevalence of Elderly

One of the fastest growing segments of developed countries is felt to be those aged 65 and over. Currently this group accounts for approximately 15% of the population in western European countries and the United States. The proportion is expected to grow to 19%-26% by the year 2025 (Elia, 2001). Experts in the field of Gerontology feel that it is especially important to focus on obesity in the elderly due to effects on morbidity and mortality compared to younger individuals (Elia, 2001). It is also important to note that due to the incidence of co-morbid conditions in this population, obesity intervention plays a key role in the management of these diseases (Physical Activity and Older Americans: Benefits and Strategies, 2002). McGinnis and Foege (1993) found that 14 percent of all deaths in the United States were felt to be attributed to inadequate nutrition and insufficient activity.

The Centers for Disease Control (CDC) data shows that 28 percent to 34 percent of adults aged 65-74 and 35 percent to 44 percent of those aged 75 or older are inactive, defined as no leisure-time physical activity. Their findings also showed that older people are more inactive than those persons who are middle aged (Physical Activity and Older Americans: Benefits and Strategies, 2002). Women over the age of 45 years old were less active as they age than their male counterparts as illustrated in Figure 1.

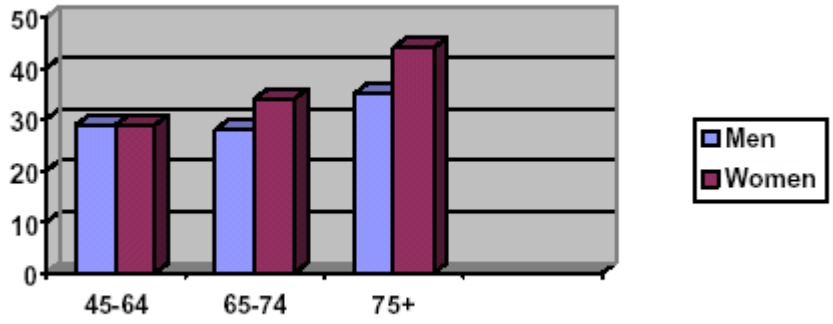

Figure 1. Physical Inactivity for U.S. Men and Women, 2000 (Percent Inactive). Source of graft from Behavioral Risk Factor Surveillance Survey. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion. http://www.cdc.gov/brfss/

National data tracked by the U.S. Department of Health and Human Services supports that few older persons engage in regular physical activity. Only 31 percent of Individuals aged 65 to 74 years reported 20 minutes of moderate physical activity on three or more days per week. Approximately 16% reported 30 minutes of moderate activity on 5 or more days per week (U.S. Department of Health and Human Services, 2000). Vigorous physical activity that produces large increases in heart rate and moderately heavy sweating produces greater gains in cardiopulmonary fitness. The individuals that participate in vigorous activity are even fewer in number and continue to decline with age (Physical Activity and Older Americans: Benefits and Strategies, 2002). The estimates for 2000 indicate only 13% of individuals aged 65 to 74 reported engaging in vigorous physical activity for 20 minutes three or more days per week. There were only six percent of those age 75 and older reporting vigorous physical activity as shown in Figure 2 (U.S. Department of Health and Human Services, 2000).

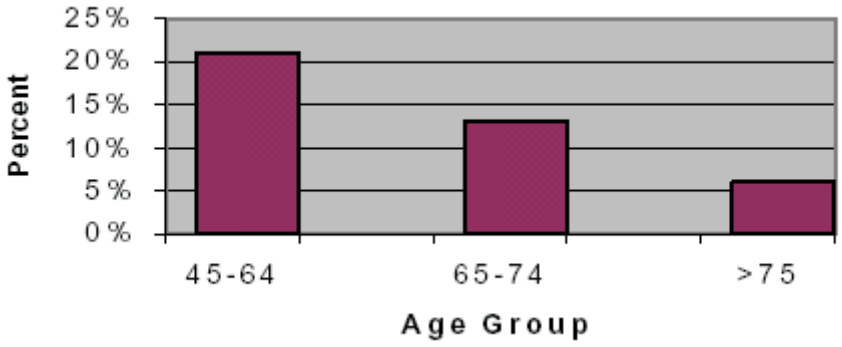

Figure 2. Vigorous Physical Activity, 2000. Data retrieved from the U.S. Department of Health and Human Services. Healthy People 2010, 2nd ed. With Understanding and Improving Health and Objectives for Improving Health. 2 vols. Washington, D.C.: U.S. Government Printing Office, November 2000. Note: Data are based on 1997 data adjusted to the age of the U.S. Population in 2000.

The growing number of aging, obese adults puts increased demands on medical, social, and public health system services. The total costs of overweight and obese in the year 2000 combined was estimated to be $117 billion (U.S. Department of Health and Human Services, 2000). In the United States, 18 percent of adults aged 65 and older were obese in the year 2000. The data also showed that another 40 percent were overweight as shown in Figure 3.

As the American population grows in number and the percentage of elderly increase, medical care costs will also continue to rise. The CDC has shown that the cost of inactive adults is substantially higher than those of their active counterparts. The excess costs are especially notable in women. It is currently felt that the data shown in Figure 4 supports that improving physical activity in elderly women stands to reap more benefits in terms of lower health care costs as compared to any other age group (Physical Activity and Older Americans: Benefits and Strategies, 2002).

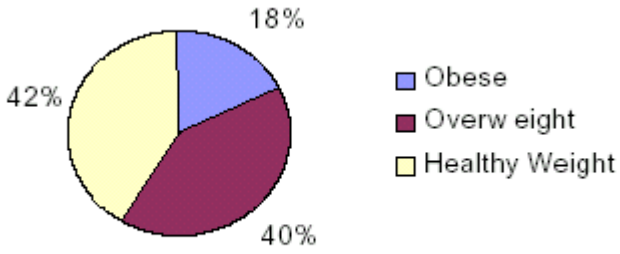

Figure 3. Percentage of Obese, Overweight, and Healthy Weight Adults > Age 65, 2000. Graft source Center for Disease Control and Prevention. National Center for Chronic Disease Prevention and Health Promotion. Behavioral Risk Factor Surveillance System. Trend Data, Nationwide. April 1, 2002 Retrieved from apps.nccd.cdc.gov/brfss/Trends/trendchart.asp?qkey=10010&state=US&grp=O&SUBMIT3=Go.

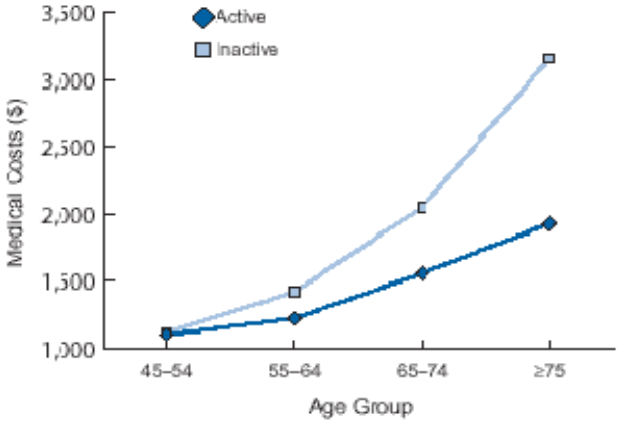

Figure 4. Annual Medical Costs of Active and Inactive Women (Aged 45 or Older) Without Physical Limitations. Figure retrieved from Centers for Disease Control and Prevention. Promoting Active Lifestyles Among Older Adults. National Center for Chronic Disease Prevention and Health Promotion. Nutrition and Physical Activity. www.cdc.gov/nccdphp/dnpa/physical/recommendations/older adults.htm

Obesity *Defined in the Elderly*

The definition of obesity currently relies upon Body Mass Index as a tool for assessing weight status. Both the National Heart, Lung, and Blood Institute of Health (NHLBI) of the National Institute of Health (NIH) and World Health Organization (WHO) now recommend 25 kg/m^2 as the upper limit of ideal body weight for all adults regardless of age (Mazzeo & Tanaka, 2001). Parameters for normal weight and obesity in the elderly are often disputed in the literature due to potential adverse effects of weight loss such as muscle wasting, nutritional deficits and catabolic disease states. A meta-analysis performed by Heiat, Vaccarino & Krumholz (2001) concluded that the federal guidelines for ideal weight (BMI 18.7 to < 25) might be too limiting for older adults. They determined that a BMI ranging from 27-30 are optimal based on all-cause and CHD mortality and CHD incidence. Some experts support the definition of obesity in the elderly as a BMI > 30. There is some debate over ideal body weight due to the concern that senior adults may benefit more from maintenance of activity versus weight loss. The concern is due to obesity related conditions that may be worsened such as sarcopenia and bone density changes during weight loss (Villareal et al., 2005). Due to these discrepancies and the increased unreliability of BMI in the elderly, researchers have suggested that a more precise measure of body fat in the older population and should utilize methods that measure three, four and/or five compartments (Villareal et al., 2005). This study will multi-compartment method for assessing body composition changes (e.g., Bioelectrial Impendence, Dual Energy Absorptometry, waist and hip measure etc.).

Physiology of Aging and the Effects of Exercise

The process of aging can impair the body's ability to regulate its internal environment. While this process occurs in all individuals, exercise can offset some of the affects of aging. The body systems and related effects of aging are represented in Table 1.

The table below illustrates how aging affects most if not all physiological processes. The onset of these changes usually begins in the third and fourth decade of life and continues to deteriorate with further aging. Fortunately for humans the body system has been shown to respond quickly despite advanced age. Obesity in the absence of intervention complicates and produces further stress on a body system and leads to cellular and system malfunction, ultimately producing a disease state. Research has shown many times over that obesity is associated with increased risk of many common, chronic diseases including heart disease, stroke, some cancers and diabetes mellitus as well as disease risk factors such as hypertension and hyperlipidemia (Patterson, Frank, Kristal & White, 2004). Obesity has also been linked but is not solely responsible for osteoarthritis (Anderson & Felson, 1988), gallstones (Stampfer, Maclure, Colditz, Manson & Willett, 1992), asthma (Redd & Mokdad, 2002), depression (Blazer, Moody-Ayers, Craft-Morgan, Burchett, 2002; Faith, Matz & Jorge, 2002) and sleep disorders (Peppard, Young, Palta, Dempsey & Skatrud, 2000). Research has shown that exercise and/or weight loss can improve or eliminate these conditions.

Table 1. *Body System and Related Effects of Aging*

Effect	Functional Significance
Cardiovascular	
Blood, plasma, and red cell volumes ↓	Decreased venous return and stroke volume
Capillary/fiber ratio ↓	Decreased muscle blood flow
Cardiac compliance ↓	Decreased early diastolic filling and increased contribution of atrial priming
Endothelial dysfunction	Decreased nitric oxide secretion; reduced blood flow control
Sodium-potassium pump activity ↓	Decreased management of cell water and electrolytes
Cardiac muscle and heart volume ↓	Decreased maximal stroke volume and cardiac output
Elasticity of blood vessels ↓	Increased peripheral resistance, blood pressure, and cardiac afterload
Myocardial myosin-ATPase ↓	Decreased myocardial contractility
Sympathetic stimulation of SA node ↓	Decreased maximum heart rate
Respiration	
Condition of elastic lung support structures ↓	Increased work of breathing
Elasticity of support structures ↓	Decreased lung elastic recoil
Size of alveoli ↑	Decreased diffusion capacity and increased dead space
Number of pulmonary capillaries ↓	Decreased ventilation/perfusion equality
Muscles/Joints/Soft Tissues	
Accumulated mechanical stress in joints ↑	Stiffness, loss of flexibility, and osteoarthritis
Action potential threshold ↓	Loss of strength and power
Blood insulin ↑	Hypertension, coronary heart disease
Ca++, Myosin)ATPase ↓	
Insulin sensitive ↓	Diabetes, coronary heart disease. Obesity, hyperlipidemia, hypertension
Lactate dehydrogenase ↓	Slows glycolysis
Muscle mass ↓	
Number of type IIa and IIb fibers ↓	
Oxidative enzymes: SDH, cytochrome oxidase, and MDH ↓	Decreased muscle respiratory capacity
Size and number of mitochondria ↓	Decreased muscle respiratory capacity
Size of motor units ↓	
Stiffness of connective tissue in joints ↑	
Total protein and N_2 concentration ↓	
Water content in intervetebral cartilage ↓	Atrophy and increased chance of compression fractures in spine
Bone	
Bone minerals ↓	Osteoporosis- increased risk of fracture
Body Composition and Stature	
Abdominal fat deposition ↑	Coronary Artery Disease, insulin resistance, hyperlipidemia, back pain
Body fat ↑	Impaired mobility and increased risk of disease
Fat-free weight ↓	Decreased metabolic rate
Kyphosis ↑	Loss of height

Note: Information within table adapted from Exercise Physiology; Human bioenergetics and its applications p. 837), by G.A. Brooks, Thomas D. Fahey & Kenneth M. Baldwin, 2005, Boston: McGraw Hill.

Cardiovascular Benefits with Exercise in the Older Population

It is well documented in the literature that regular physical activity can prevent Coronary Heart Disease (CHD) and/or treat and prevent CHD risk factors, including hypertension, insulin resistance, glucose intolerance, elevated triglycerides, low HDL-cholesterol levels and obesity (American Heart Association Council, 2003). The relative risk of CHD associated with a low physical activity level, ranges from 1.5 to 2.4, an elevation that is similar to the risk of hypertension, high cholesterol levels or smoking (American Heart Association, 2004). Exercise results in positive cardiovascular changes in older adults according to intervention studies (Houde & Melillo, 2002). The Cardiovascular Health Study concluded that engaging in physical activity was associated with remaining healthy over a seven year period of follow-up in 5,888 men and women over age 65 (Marwick, 1997).

Unfortunately the medical community may not support the importance of preventive exercise and nutrition intervention because less than fifty percent of older adults report that their physicians have recommended exercise (Darmush, et al., 1999). A Scandinavian study concluded that older patients who received exercise counseling from their physicians were five to six times more likely to participate in supervised exercise classes (Hirvensalo, Heikkinen, Lintunen, Rantanen, 2003).

Cardiovascular Changes in Aging

Previous research shows that maximal oxygen consumption ($V0_{2\ max}$) decreases with age by approximately 30% between the ages of 20 and age 65. It has also been shown to decrease greater after age 40. These findings also have variability due to training adaptations. For example, master athletes who run can have a higher $V0_{2\ max}$ than

a sedentary 20 year-old (Brooks, Fahey & Baldwin, 2005). The changes in $V0_{2\ max}$ have been shown to be due to the following parameters: maximal heart rate, stroke volume, power output capacity, fat-free mass, and arteriovenous oxygen difference. In the aging person there are anatomical and physiological changes that significantly affect response to exercise. These changes include reduced pulmonary function (decreased vital capacity, forced expired volumes), impaired cardiovascular function (decreased cardiac output, stroke volume, maximal heart rate, exercise capacity and baroreceptor function) (Chandler & DiCarlo, 1994).

Aging is associated with a decline in parasympathetic withdrawal and β-adrenergic responsiveness. The reduced parasympathetic tone in aging results in an increased resting heart rate and an initial abated response to exercise due to the delay in vagal activity. A slower heart rate response in aging allows for ventricular filling during exercise (Chandler & DiCarlo, 1994). This change results in increased end diastolic volume, allowing for an increased stroke volume. Other limited factors affecting the aging heart include: increase in afterload (resulting from stiffening in the arterial system), a diminished response to beta adrenergic agonists that lessen the increase in contractility, decreased ventricular compliance limiting the increase in end diastolic volume. All of the aforementioned changes result in an attenuated stroke volume response during exercise. The aging heart will not have an increased ejection fraction due to the increased end-systolic volume (Chandler & DiCarlo, 1994).

In the pulmonary system reserve capacity declines during the ages of 30 to 60 years old. The three areas that seem to contribute greatly to this process are: size of the alveoli, disintegration of the elastic architecture of the lungs, and loss of strength in

pulmonary musculature. Physiologic changes associated with aging can also be exacerbated in the presence of pulmonary disease. The process of ventilation and supporting musculature may be improved via exercise (Brooks et al., 2005).

Testing used to measure cardiopulmonary fitness in the elderly population includes maximal, sub-maximal stress testing and functional walking tests. The current ACSM guidelines recommend maximal stress testing in this age group prior to exercise prescription (ACSM, 2000). The direct measure of $VO_{2\ max}$ capacity is the most accurate method in determining cardiovascular fitness. The maximal stress test also allows screening underlying heart disease as well as exercise tolerance. The six minute walk test, a measure of functional aerobic capacity can be used in any chronic disease population and can be easily reproduced in the field. Previous studies in the geriatric population have made the observation that one in five elderly patients (70 years and over) is unable to execute the classic treadmill based exercise test, due to fear of falling or because of physical or cognitive limitations (Bautmans, Lambert, & Mets, 2004). This mode of testing will be utilized and compared to direct VO_2 testing. This test better simulates daily activity and is considered an excellent measure of exercise endurance (Steffen, Hacker & Moolinger, 2002).

Exercise Recommendations and Effects on Aging

The current guidelines by the CDC and the American College of Sports Medicine (ACSM) recommend 30 minutes per day on most days of the week. Research has shown that these guidelines allow men and women to experience decreased rates of cardiovascular disease and premature mortality (Lee, 2003). The NIH has done extensive research in the area of exercise intervention in promoting health and established the

following guidelines. Weight loss is recommended to lower elevated blood pressure in overweight and obese persons with high blood pressure. Exercise is also strongly recommended to lower elevated levels of total cholesterol, LDL-cholesterol and triglycerides and to raise low levels of HDL-cholesterol in overweight and obese persons with dyslipidemia (Mazzeo & Tanaka, 2001). If weight loss is achieved it can lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes. The combination of a reduced calorie diet and increased physical activity is recommended, since it produces weight loss, decreases abdominal fat, and increases cardiorespiratory fitness (Mazzeo & Tanaka, 2001).

Due to research supporting that older women are higher risk in regards to inactivity, obesity and fall risk, innovative programs are needed to meet the needs of this population. Curves International has had an overwhelming response by those who would not ordinarily frequent a gym or workout center as evidenced by the 10,000 centers world wide. The 30 minute circuit and nutrition plans are offered in a women's only environment that allows the female population to feel less intimidated in pursuing weight loss and a higher level of fitness. This environment also allows for socialization and accountability by their peers and work out supervisors. Members of the Curves International clubs are able to provide support to each other in a non-intimidating setting that has the added benefit of work out attendants providing support, encouragement and assistance with machine use and technique.

Kreider, et al. (2005) has shown that women following this program for 14 weeks lost 10-14 pounds, decreased body fat by 1-3%, increased resting energy expenditure by 100-400 kcal/day, and had a reduction in waist & hip measurements of 1.5-2 inches.

Maximal aerobic capacity increased by 10% and muscular strength/endurance improved by 10-15%. Resting heart rate values decreased by 3-5 beats/min. Lipid panel changes showed total cholesterol decreased by 4%, LDL decreased by 3%, triglycerides decreased by 12%. An overall reduction in leptin was shown to be 17%. In addition, fasting insulin was reduced by 15% overall, while insulin sensitivity improved by 19%. Body image, self-esteem, and quality of life increased among the participants. Biomechanical and energy expenditures analysis performed on the Curves fitness and program indicated that exercise intensity of 65% of $VO_{2\ max}$ support the ACSM guidelines. Women new to exercise can burn approximately 164-238 kcals during a 30-minute Curves workout. Highly trained women can burn 238-522 kcals/30 minute-workout at 65% $VO_{2\ max.}$ In addition, the strength training components of the program indicated a 50-75% of 1RM with an average of 15-20 repetitions performed per 30-second time frame (Campbell, et al., 2006). As a result, the research has shown that the Curves program is highly effective in promoting weight loss, improving markers of health, and improving fitness.

Cardiovascular fitness may be obtained at any age (American Dietetic Association, 2005). Another advantage of consistent exercise is the ability to prevent and/or reduce declines in functional ability that is often viewed as normal aging (Chernoff, 2006). Some positive effects of exercise help offset conditions that the general public views as inevitable during the aging process. Some of these conditions include improved bone health with subsequent reduction in risk of osteoporosis, improved postural stability, reducing the risk of falling and possible fracture, as well as increased flexibility and range of motion.

It has been established that weight loss in obese older populations can improve functional fitness, overall health and independence. The cardiovascular system is one critical body system that steadily decline with age. For example, $VO_{2\ max}$ declines approximately 30% between the ages of 20-65. The greatest rate of VO_2 decline occurs after the age of 40 (Noakes, Keogh, Foster & Clifton, 2005). One area in the elderly that contributes significantly to VO_2 levels is decreased muscle mass. The loss of muscle mass and subsequent strength can profoundly affect the quality of life in the elderly. The lack of muscular support can affect stability, functional capacity for activities of daily living and metabolism. All of these factors can cause and/or exacerbate obesity (Noakes, Keogh, Foster & Clifton, 2005). Research done in younger age groups utilizing the Curves circuit and nutrition plans, it has been shown that cardiovascular benefit and maintenance of muscle mass during weight loss are obtainable (Kreider, 2005).

Metabolic Disorders in the Obese Elderly

According to current estimates, over 50 million and perhaps 75 million Americans meet criteria for metabolic syndrome (Peterman, Farooq & Roberts, 2004). The criteria include: abdominal obesity (waist size > 40 inch in men or > 35 inches in women), triglycerides ≥ 150 mg/dL, HDL < 40 mg/dL in men or < 50 mg/dL in women, systemic hypertension (BP > 130/85 mm Hg), and fasting blood glucose > 110 mg/dL. It is also current knowledge that weight loss decreases diastolic blood pressure and serum LDL cholesterol, triglycerides, insulin, glucose and increases HDL cholesterol (Peterman, Farooq & Roberts, 2004).

Based on the defining characteristics noted above in diagnosing Metabolic Syndrome, waist to hip (WHR) measures and waist circumference (WC) play an integral

part in assessing risk for metabolic disorders and have been proven to be a better indicator of cardiovascular risk. Schneider et al. (2006) looked at whether WHR or WC are more sensitive measures for visceral obesity and which measure may be more indicative of cardiovascular risk. This group of researchers studied 5,377 unselected subjects (2,016 men and 3,361) women) without arteriosclerotic disease, aged 20-79 years from the DETECT (a cross-sectional, clinical-epidemiological study) laboratory sample in a primary care setting. The intervention included measuring anthropometric parameters and assessing CHD risk by clinical exam, patient history, and a standardized laboratory program. The associations of BMI< WC, hip circumference, WHR and waist-to-height ratio (WHtR) to cardiovascular risk by calculating the area under the receiver-operating characteristics (ROC) curve in combination with adjusted odds ratio for metabolic syndrome, dyslipidemia and type 2 Diabetes. Their results showed the area under the ROC curve for WHtR was significantly higher than for all other anthropometric parameters with respect to all risk conditions in women and to dyslipidemia and Diabetes Type II in comparison to men. The odds ratio for presence of risk conditions with one standard deviation increase of each anthropometric parameter was highest for WHtR or WC. They concluded that there are some indications that WHtR or WC may predict prevalent cardiovascular risk better than BMI or WHR despite the small differences noted in this study (Schneider et al., 2006).

Some researchers have tested whether both may be a better determinant of cardiovascular risk than either alone. Zhu et al. (2004) put this theory to the test by combining waist circumference (WC) and BMI in evaluating 8,712 white men and women from the Third National Health and Nutrition Examination Survey. The optimal

combination of BMI and WC using current cut-off points was also examined. Specificity, sensitivity, and receiver operating characteristics curves were compared between the combined measures and BMI alone. The results showed that for white men, the optimal combination of BMI and WC for the identifying CHD risk factors was 0.68 x BMI + 0.32 x WC. This combination generated a score that better estimated the odds of having CHD risk factors than either alone. For white women, WC alone largely determined the likelihood of having CHD risk. Combined measures showed a higher sensitivity or a shorter distance in receiver operating characteristic curves in the identification of CHD risk factors. Their conclusions support combining measures of BMI and WC so a higher overall test performance for CHD risk factors may be utilized in some ethnic groups as an improved screening tool (Zhu et al., 2004).

Despite the means of measure, it is well known that obesity is a major risk factor for the development of chronic diseases and mortality (The World Health Report, 2002; Mokdad, Marks, Stroup & Gerberding, 2000; Fiegal, 2005). The risk of CHD increases with increased BMI (Fiegal Graubard, Williamson & Gail, 2005). There have also been several prospective studies that have shown that increased abdominal fat accumulation is an independent risk factor for type 2 diabetes mellitus as well as cardiovascular risk conditions such as CHD, stroke and hypertension (Larsson et al., 1984; Lapidus et al., 1984); Ducimetiere, Richard & Cambien, 1986). The accumulation of visceral fat is associated with increased free fatty acid (FFA) secretion, hyperinsulinemia, insulin resistance, hypertension and dyslipidemia (Wajchenberg, 2000; Carr & Brunzell, 2004).

Since Gerald Reavins established the diagnosis of Syndrome X in 1988, now called metabolic syndrome, there have been new insights shed in the manifestations of

this disorder. Insulin resistance once thought of as one of four components of Metabolic Syndrome is now thought to be the single dominant factor predicting this pathology (Reaven, 1988; Reaven, 2003). Insulin resistance occurs at the cell membrane and is an early indicator of disease.

Serum Markers

The physiological affects from obesity can affect the entire body system. The deposition of intraabdominal fat and sarcopenic obesity can alter metabolic pathways and lead to excess energy (fat) redirected towards peripheral organs. The excess lipids can also enter non-oxidative pathways resulting in production of toxic, reactive lipid species (Slavik & Vidal-Puig, 2006). This process can lead to lipotoxicity induced apoptosis. The accumulation of these reactive lipids can be found in organs such as the liver and heart. The alterations in metabolism and fat deposition play a major role in the development of comorbidities of obesity which include: coronary artery disease, stroke, type 2 diabetes, hypertension, dyslipidemia, musculoskeletal disorders, some cancers and deep vein thrombosis (Slavik & Vidal-Puig, 2006). There are also hormonal mechanisms associated with obesity that include abnormal alterations in leptin, ghrelin, insulin and/or adiponectin.

Insulin, one of the most powerful hormones produced by the body is a major regulator of glucose metabolism. One primary regulator of basal insulin secretion between meals is the presence of fatty acids (Bollheimer et al., 1998). In obesity, there is an overabundance of free fatty acids secreted from a large reservoir of adipose tissue. Plasma free fatty acids are presented to the pancreatic β-cell via intracellular metabolism (like glucose). Through newly described cell surface (G-linked) receptors (Poitout, 2003)

enhance insulin release. The downstream effects at the adipocyte dampen lipolysis, enhance reesterification of fatty acids, and reduce plasma-free fatty acids to more normal levels (Roth, Qiang, Marban, Redelt & Lowell, 2004). The fatty acid regulation of basal insulin secretion between meals serves as a significant determinant of whole body "insulin sensitivity". Persistent elevation of free fatty acid levels has direct effects on metabolism in muscle and liver, dampening the effect of insulin (Perseghin, Petersen & Shulman, 2003; Randle, Garland, Hales & Newsholme, 1963; Kim, Gimeno & Higashimori et al., 2004). The continued process of adipocyte hypertrophy (e.g., fat mass) produces an oversupply of fatty acids in the blood that contribute to metabolic disturbances via many pathways in the obese (Roth et al., 2004). Sustained elevated levels of insulin, despite the cause, typically leads to generalized insulin resistance (Roth et al., 2004). In transgenic mice, hyperinsulinemia caused insulin resistance, reduced insulin-receptor binding as well as increased triglycerides (Roth et al., 2004). This findings supports that hypersecretion of insulin can both be a "cause of and a result of insulin resistance" (Roth et al., 2004). The presence of cytokines adds to the complex state of obesity (Bruunsgaard & Pedersen, 2003; Qiang, Yang, Tracey & Roth, 2004; Dandona, Aljada & Mohanty, 2002; Liang, Han, Okamoto et al., 2004; Pirola, Johnston & Van Obberghen, 2004; Krogh-Madsen et al., 2004; Hotamisligil, 2003; Dandona, Aljada & Bandyopadhyay, 2003). TNF-α can produce insulin resistance at the level of target cells for insulin (Roth et al., 2004). In research on obese mice, the insulin resistance of macrophages is associated with hypersecretion of cytokines and the enhanced density of macrophages found in fat depots bolsters the idea that cytokines play a major role in insulin resistance (Roth et al., 2004). Despite the complexity of insulin

resistance and cell signaling, one key intervention in treating the obese patient remains to be moderate caloric restriction, moderate exercise, 5%-10% weight loss and prevention and treatment of co-morbid conditions associated with obesity (Roth et al., 2004).

Adipose tissue has been referred to as one of the largest endocrine organs, having paracrine, autocrine and endocrine function (Slavik & Vidal-Puig, 2006). It's affects on the body system have also been shown to differ by location. Adipose tissue plays a role in regulating body weight. It secretes products such as leptin, adiponectin, interluekin-6, TNFα, angiotensinogen, plasminogen activator-inhibitor 1 (PAI-1), adipsin (complement factor D), sex steroids, and glucocorticoids. Many of these products have been present in the literature since the mid-1990s but were not always connected to obesity (Bray & Bouchard, 2004). These hormones play an intricate role in the etiology of obesity. Leptin, a cytokine-like polypeptide, can have an affect on long-term control of energy intake, whereas ghrelin and insulin appear to have short-term impact on energy intake (Bray & Bouchard, 2004). Insulin, an anabolic hormone, has the known function of direct storage and utilization of energy in adipocytes. In obesity, insulin is often in abundance in the body. Insulin is often found in high amounts due to the lack of communication between insulin and its receptor located on the cell membrane. Insulin secretion subsequently increases by the beta cells of the pancreas (Bray & Bouchard, 2004). Abdominal obesity and Type II Diabetes have proven to be related to insulin resistance. Leptin and adiponectin have also been shown to play a role in insulin regulation. They both have been linked to increase insulin sensitivity and leptin has been shown to decrease insulin secretion. Leptin and other anorectic cytokines may also mediate levels of ghrelin, a growth hormone secretagogue. Ghrelin is found in high

concentrations in the stomach and its expression and secretion increases with fasting. This area of research shows a lot of promise in better understanding the pathophysiology of obesity on a cellular level (Bray & Bouchard, 2004). Adiponectin, a protein secreted by adipose tissue, is present at lower levels in the obese. It has been shown to affect different aspect of the immune system and subsequent inflammatory responses. Low levels of adiponectin have been associated with cardiovascular disease, diabetes and insulin resistance (Bray & Bouchard, 2004).

Hyperlipidemia, defined as abnormal lipid levels is a known risk factor for Coronary Heart Disease (CHD). In particular, concentrations of total cholesterol and low-density lipoprotein (LDL) cholesterol have been highly correlated with CHD. Low levels of High density Lipoprotein (HDL) are an individual risk factor for CHD. Elevated triglycerides are also associated with CHD and often co-exist in those with low HDL and high LDL. Triglycerides also respond very well to non-drug therapy. Pharmaceutical companies track prescription compliance of statin therapy and have noted that approximately 30% of patients initiated on statins do not continue their prescriptions (Rosenthal, 2000). Due to the financial burden of these drugs, many patients admit to taking their medicine every other day or a few times a week to decrease cost. Outcome studies on statin therapy base results on daily compliance. Recent literature also suggests that abrupt stoppage of this medication may be more harmful than not initiating therapy. In the elderly population, it is often debated whether long term statin therapy benefits out way the risks. These drugs are financially taxing and can cause unpleasant symptoms as well as negative side effects in muscle and liver tissue. Due to the multi-system benefits of exercise, this population stands to reap tremendous benefit from lifestyle modification.

Fahlman, Boardley, Lambert & Flynn (2002) examined the relationship between exercise and plasma lipoprotein levels in the elderly population. The purpose of the study was examining the effects of endurance and resistance exercise on plasma lipoprotein levels in elderly women who were active but non- exercising prior to the study. The total number of participants equaled 45 healthy, active women, aged 70-87 years, randomly assigned to either an aerobic training (AT, n=15), resistance training (RT, n=15) or control (C, n=15). The AT group walked three days a week at 70% heart rate reserve. The duration on day one was 20 minutes, and the time increased by five minutes each day until participants were walking a total of 50 minutes per session (week 3). The training session for the RT group consisted of one to three sets of an eight repetition maximum. The C group maintained their normal routine. Weight and diet were unchanged across groups. The interventions lasted a total of ten weeks. Serum blood samples were obtained at week zero and eleven. The AT training group had significant decrease in 1-mile walk times and heart rate at completion of the walk and there was a significant increase in eight repetition maximum of all RT exercises. Both the AT and RT groups experienced increased HDL cholesterol and decreased triglycerides at week 11 in comparison to week 0. There were no positive changes in lipoproteins for the control group. Both triglycerides and the total cholesterol to HDL ratio increased significantly while total cholesterol, HDL cholesterol and LDL cholesterol remained unchanged. The RT group also had significant lower LDL cholesterol and total cholesterol compared with controls at week 11. Both resistance and endurance training resulted in favorable changes to plasma lipoprotein levels for elderly women in only ten weeks. These changes occurred without changes in weight or diet. The researchers

concluded that high-intensity exercise alone can be used to modify lipoproteins in healthy elderly women (Fahlman et al., 2002).

Aging and Muscle Morphology

In the human aging process, there is a significant decline in neuromuscular function and performance. One main characteristic of this decline is the inevitable reduction in skeletal muscle mass and the associated loss of strength that occurs even in the healthy elderly (Doherty, 2003). This prevalent, physiological result of aging is a condition called sarcopenia. Sarcopenia is defined as the loss of muscle mass that is primarily due to disuse. However, the loss of muscle mass can be accelerated by inactivity, poor nutrition and chronic illness. The loss of muscle mass is currently felt to be approximately 5% per decade after the 4^{th} decade of life and is currently thought to occur more rapidly after age 65 (Greenlund & Nair, 2003). It is also current knowledge that the impact of muscle loss and function in women may be greater due to a lower initial muscle mass compared to men (Greenlund & Nair, 2003).

Table 7 below depicts a simplified summary of the alterations in muscle physiology with aging and post exercise intervention.

The advancement of techniques such as muscle fiber typing has allowed for increased knowledge in the area of muscle fiber changes through the lifespan and in studying training adaptations. ATPase staining techniques are utilized to assess changes in Type I and II muscle fibers and their respective phenotypes.

Table 2. *Summary of Muscle Adaptation to Aging and Training in the Elderly adapted from Kirkendall et al., 1998.*

Variable	Aging	Training
Muscle mass	Decrease	Increase or no change
Type I %	Increase	No change
Type II %	Decrease	No change
Type I area	No change	Increase
Type II area	Decrease	Increase
Oxidative capacity	Decrease	No change
Glycolytic capacity	No change	Increase
Capillary density	Decrease	Increase
Relaxation time	Increase	Decrease or no change
Shortening velocity	No change	Increase

Type I fibers are predominantly comprised of myosin heavy chain 2a (MHC 2a), and type IIB fibers are predominantly myosin heavy chain 2x (MHC 2x). Current literature supports that mRNA levels of MHC 2a and 2x decrease with age (Balagopal, Schinke, Ades, Adey, & Nair, 2001). Slow twitch type I fibers are fatigue resistant with greater oxidative capacity, higher mitochondrial content, and greater capillary density. Type II fibers are fast-twitch fibers with a high glycolytic capacity. Type II fibers can be classified into type IIA, having intermediate oxidative and glycolytic capacity and are more fatigue resistant. Type IIB and IIC are more glycolytic. In a comprehensive study looking at muscle fiber changes in the vastus lateralis, 43 male cadavers were examined between the ages of 15-83, showed an age-related loss in fiber number and between the ages of 20 and 80 there is about a 50% reduction in the total fiber number (Lexell, Taylor & Sjostrom, 1988). This loss has been noted to be more rapid over the age of 50. Measurements of a cross sectional area of muscle, show a selective loss of fast-twitch type II fibers in comparison to slow-twitch type I fibers. This shift in aging appears to be

independent of vigorous endurance exercise based on muscle biopsies taken from a 20-year longitudinal study of distance runners (Trappe, Costill, Fink, & Pearson, 1995).

Metabolic Consequences of Sarcopenia. The metabolic consequences of muscle mass decline have been well documented in a number of cross-sectional and longitudinal studies. The reduction in muscle mass significantly affects the amount of metabolically active cell mass. Previous research supports a 15% decline in resting metabolic rate between age 30 and 80 (Calloway & Zannie, 1980; Fukagawa, Bandini, & Young, 1990; Poehlman & Horton, 1990b; Vaughan, Zurlo & Ravussin, 1991). This estimated decline corresponds with a decrease of 250 kcals burned per day. A decline in total energy expenditure is also impacted by a decrease in physical activity. The decline in physical activity is often due to age-related muscle weakness, fatigability, and loss of endurance. Unfortunately, the loss of muscle mass in aging is accompanied by gains in fat mass. This process is exacerbated by decreased daily expenditure and daily activity. The decline in function adds to the age-related accumulation of visceral, total body fat and decreased insulin sensitivity. This constellation of changes increases the likelihood of Type II Diabetes (Kohrt & Holloszy, 1995). Due to the loss of muscle mass in the elderly, which serves as the main metabolic organ responsible for glucose disposal and fatty acids post meals, post prandial hyperglycemia is also more common (Greenlund & Nair, 2003).

Protein Synthesis Mechanisms of Sarcopenia. The balance between protein synthesis and protein breakdown is the main contributor to the maintenance and repair of skeletal muscle. Muscle quality and mass are reliant upon the efficient synthesis of new structural proteins. Previous research has shown that the synthesis of mixed muscle

protein is reduced by 30% with age (Welle, Thorton, Jozefowicz, & Statt, 1993; Welle, Thorton & Statt, 1995; Balagopal, Rooyackers, Adey, Ades & Nair, 1997). This selective decrease in muscle protein synthesis may explain the age-related decrease in muscle mass (Greenlund & Nair, 2003).

Mitochondrial Dysfunction. The number and function of mitochondria have been associated with the degree of muscle fatigability, reduced endurance capacity, and possibly loss of strength. The ATP generated by mitochondria play a crucial role in generating contractile force. It has been shown that aerobic exercise can significantly increase mitochondrial enzyme activity. In men and women aged 60-70 who trained for 9-12 months by walking or jogging at 80% of maximal heart rate for 45 minutes, 4 days per week had a 24% increase in mitochondrial enzymes succinate dehydrogenase, citrate synthase, and beta-hydroxyaacyl-CoA dehydrogenase (Coggan et al, 1992).

Nutrition and Sarcopenia. The phenomenon termed anorexia of aging may be one of the biggest modifiable variables to the development and progression of sarcopenia (Doherty, 2003). This condition is simply defined as the decline of food intake over the lifespan. There are many complex mechanisms and interactions that contribute to decreased food intake including: early satiety secondary to decreased relaxation of the fundus, increased release of cholecystokinin in response to fat intake, and increased leptin levels. The elevation of leptin levels are thought to be in part due to increased fat mass with aging. Other contributors include effects of neurotransmitters such as opiods and neuropeptides (Morley, Baumgartner, Roubenoff, Mayer & Nair, 2001).

Hormonal Influence on Sarcopenia. Hormone therapy has also shown promise in combating age related muscle mass loss. The hormones that have received the most

attention include testosterone, growth hormone (GH), Insulin-like growth hormone (IGF-1) and dehydroepiandrosterone (DHEA) (Greenlund & Nair, 2003). Bioavailable levels of testosterone have been shown to be decreased, especially in the years immediately following menopause. In post hysterectomy patients with oopherectomy, bioavailable testosterone levels have been noted to be even lower due to the loss of ovarian androgen production (Judd, Lucas & Yen, 1974; Laughlin, Barrett-Conner, Kritz-Silverstein & von Muhlen, 2000). Women taking estrogen replacement therapy may have a further reduction in bioavailable testosterone by binding more androgen. Testosterone supplementation in elderly women needs further study (Greenlund & Nair, 2003).

It is current knowledge that growth hormone and its peripheral mediator, IGF-1 decrease with age (Rudman et al., 1981; Ho et al., 1987; Poehlman & Copeland, 1990a). Deficiency in growth hormone leads to muscle mass loss and increased adipose tissue. The benefits and effects of growth hormone replacement in the elderly continue to be controversial. Supplementation with recombinant growth hormone or IGF-1 in elderly women has been noted to increase net protein synthesis (Butterfield et al., 1997). These changes may lead to increased muscle mass. There are numerous studies in elderly males that failed to show beneficial effects from growth hormone in relation to muscle protein synthesis or strength compared to exercise alone (Greenlund & Nair, 2003). It is also important to note significant adverse effects due to growth hormone administration that contribute to study withdrawal. These adverse effects include fluid retention, carpal tunnel compression, gynecomastia, and arthralgias (Cohn, Fellar, Draper, Rudman & Rudman, 1993; Yarasheski & Zachwieja, 1993).

DHEA and DHEA-S, its sulfated form, are produced by the adrenal cortex. The exact biological role of these hormones is not well elucidated. It is currently thought that DHEA levels slowly decline after the second decade of life. The decline is linear and felt to be approximately 10% per decade until age 80 when the decline is more rapid thereafter (Rosenfield, Rosenberg, Fukushima, & Hellman, 1975; Gray, Feldman, McKinlay & Longcope, 1991; Birkenhager-Gillesse, Derksen, & Lagaay, 1994). Study results on DHEA supplementation have mixed findings. It is currently thought to have no effect on insulin sensitivity, resting metabolic rate, total energy expenditure, and muscle protein synthesis rates (Usiskin et al., 1990; Welle, Jozefowicz & Statt, 1990; Morales, Nolan, Nelson & Yen, 1994; Schriock, Buffington, Givens & Buster, 1994).

Perfusion and Sarcopenia. The delivery of oxygen and fuel to muscle tissue is dependent upon a vast capillary network. This intricate delivery system can be significantly altered due to partial occlusion of vessels by atherosclerotic plaque and defects in arterial compliance. Other age associated conditions such as hypertension can reduce blood flow and compromise oxygen delivery. Hypertension occurs in more than two thirds of those over age 65 (Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, 1997). The changes noted above are more common in the elderly and can profoundly impact protein synthesis and mitochondrial function. The degree of these effects remains to be defined (Greenlund & Nair, 2003).

Neuromuscular Influence on Sarcopenia. The progressive loss of innervations, motor neurons, and muscle stimulation play a crucial role in age-related muscle dysfunction and atrophy. Muscle denervation leads to atrophy. The result of this insult

decreases muscle mass to less than one half its original weight within a month (Greenlund & Nair, 2003). Tomlinson and Irving (1977) studied motor neuron quantification in the entire lumbosacral spinal cord of 47 individuals aged 13-95. After the age of 60, there was as much as a 50% loss of neurons in the elderly compared to young or middle aged subjects.

Interventions for Sarcopenia. There is an abundance of research supporting the fact that older people have "trainable" physiology and will reap many health benefits from exercise. It is currently felt that prevention of age-related muscle loss is the key to healthy aging. Exercise research has shown the greatest promise for both prevention and treatment of sarcopenia. Ades, Ballor, Ashikaga, Utton & Nair (1996) looked at a group of community dwelling men and women over the age of 65. Participants were randomized to either a weight-training or no training program for 3 months. The intervention group showed significant improvements in both leg strength and walking endurance. Resistance training has also been shown to be effective in the very old. Fiatarone et al. (1994) looked at nursing home residents with an average age of 87. They underwent a 10-week resistance training and nutritional intervention, showing gains in strength, improving by 125% compared to less than a 3% change in the control group. Other benefits included improved gait velocity, stair-climbing power and spontaneous physical activity. Through training adaptation, muscle physiology is enhanced via increases in muscle fiber size and muscle protein synthesis in response to resistance training (Welle et al., 1995; Yarasheski et al., 1999; Hasten, Pak-Loduca, Obert & Yarasheki, 2000; Balagopal et al., 2001). Increases have also been shown to occur in

specific muscle proteins such as myosin heavy chain, which is considered to be the key contractile protein (Balagopal et al., 2001).

The process of sarcopenia is complex and has a profound impact on numerous body systems. Although it has yet to be proven that there is a clear cause and effect relationship between muscle mass loss and physiological changes, it is currently felt that reduced synthesis rates of specific muscle proteins, mitochondrial dysfunction, poor nutrition, reduced anabolic hormone levels, alterations in perfusion, altered innervation and reduced physical activity can all be temporarily correlated to a decrease in muscle mass loss. In order to offset these losses further intervention in the area of exercise and nutrition are needed to slow the aging process as well as maximize functional capacity in the aging adult.

Functional Capacity in the Elderly

The definition of functional capacity is defined as the "maximal output or ability of a person to perform natural and expected activities within the framework of environmental circumstances" (Mangen, & Peterson, 1984). The simplest definition of functional assessment is the evaluation of "a person's ability to carry out basic activities of daily living", and is considered to be the "lingua franca" of geriatrics (Kane & Kane, 2000). Functional capacity of an aging adult is a common pathway that all practitioners share. Experts in the field of Gerontology often argue that chronological age is at best a poor barometer of the actual capacity of older individuals. Research in the area of gerontology assists other disciplines in assessing and determining the best interventions to benefit this population.

The leading cause of injury deaths and disabilities among older adults (i.e., persons aged ≥65 years) is fall-related injuries. Hip fracture is the most threatening fall related injury. Approximately one half of all older adults never regain their former functioning level after hospitalization (Stevens & Olsen, 2001). Other risk factors include increasing age, muscle weakness, functional limitations, environmental hazards, use of psychoactive medications, and a history of falls all increase risk of falls. Mobility and functional capacity are severely impacted by changes in muscle mass. In the human lifespan, the loss of muscle mass after the age of 30 is felt to be approximately 10% every decade (Noakes, Keogh, Foster & Clifton, 2005). It is currently felt that falls in the elderly are associated with age-related loss of muscular endurance and strength. An exercise intervention program that has been shown to modify these risk factors should include the following: upper/lower body strength, lower limb range of motion (flexibility), balance, and reaction time. The literature reviews that have been conducted on studies to determine success have shown that fall incidence has decreased when the intervention includes lower body strength and endurance (Stevens & Olsen, 2001).

Functional assessment enables the practitioner to identify strengths and limitations that can be considered in determining how the participant can best care for themselves. Functional capacity assessments may also be used to determine future health care costs as well as determine future living arrangements and services. In adult populations over age 65, approximately 30% will sustain a fall, and half of those will experience multiple events (Wong, Lin, Chou, Tang & Wong, 2001). Serious injuries as well as soft tissue injuries occur in 10-15% of these falls (Wong et al., 2001). Previous research shows that impaired balance and decreased lower extremity strength are key risk

factors in occurrence of falls and lowered physical functioning in older adults (Wong et al., 2001).

Purposeful exercise and recreational activities have been shown to offset functional decline in this population. In older adults, physical fitness is crucial to coping with, everyday activities as well as navigating unforeseen events. These unexpected events can come in the form of walking uphill, across uneven ground or recovering from a misstep. The literature over the past 50 years has shown decreased activity with age advancement. This is attributed to the rising use of labor saving devices and the overall mechanization of our society. The debilitating affects of inactivity are very visible in our aging American population. The Allied Dunbar National Fitness Survey found that in those citizens over 50, approximately 40% were inactive (Skelton, 2001). In the 70-75 year old women, the inactivity level was at 80% compared to 25% in the male population. The sedentary women over 70 years of age were unable to complete simple tasks such as walking a quarter mile on their own (Skelton, 2001). Decreased physical capacity can lead to senior adults reaching a "critical threshold" of performance that is necessary for everyday activities. Strength, balance, and co-ordination appear to be the major elements involved in maintaining upright posture in dynamic situations (Skelton, 2001). Previous research has supported that if areas such as upper and lower body strength, balance, flexibility and coordination improve functional fitness gains may allow activities of daily living to be performed more easily (Simons & Andel, 2006).

During the aging process, performing tasks while leaning or weight shifting subsequently alters center of gravity (COG) and can profoundly affect tasks associated with activities of daily living. Dynamic postural control is compromised in elderly adults

and increases risk for falls during ADL tasks. In comparing younger adults, the subtle changes noted in the elderly include: smaller voluntary center of gravity (COG) excursions, reaching maximal lean more slowly, and exhibiting less postural control once at maximal lean. These differences can be further compromised in the presence of medical diagnoses and physical de-conditioning states (Clark & Rose, 2001).

The NeuroCom SmartEquitest system will be utilized in this research study to quantitatively assess parameters such as these that are involved in functional capacity. These tests include the Step Up and Over (SUO) test, the Sit to Stand (STS) test, Limits of Stability (LOS) and the Sensory Organization Test (SOT). This system is frequently used in the elderly population to quantitatively assess strength, balance, functional capacity, and central nervous system changes, and has been proven valid and reliable in quantifying subtle changes in parameters associated with balance and functional ability. In fall assessments, it provides information on postural balance, vestibular function and can estimate the ease or difficulty in performing activities that mimic physiologic conditions of daily tasks such as the step up and over test and sit to stand movements (Ben Anchour Lebib, Missaoui, Ben Salah & Dziri, 2006). The assessments will include two tests that are often used to assess functional impairments and two tests used to assess functional limitations. The tests used in this study for functional limitations include the SUO test and the STS test. The tests that are often used for functional impairment purposes include the LOS and SOT. Data for this system is beneficial because self reported function does not provide adequate information regarding the type of impairment and lacks the ability to assess sensitivity to change (Cress, et al., 1996).

The SmartEquitest offers a myriad of diagnostic and functional assessments however the diagnostic tests performed for this research study will only include the LOS and the SOT. The Limits of Stability test assesses voluntary control of body positioning, coordination and timing. The LOS can also provide information used to diagnose Central Nervous System (CNS) movement disorders. For the purposes of this study, these techniques will only be used for assessing changes and improvements in postural stability; the data will not be used for diagnostic purposes.

In previous research, the majority of balance testing has been conducted in the area of Tai Chi and its benefits on aging individuals. Research has shown that exercise has produced favorable results in the area of balance and proprioception. Tsang and Hui-Chan (2003) compared experienced Tai Chi participants with experienced golfers. They compared 12 experienced golfers with 11 Tai Chi practitioners, 12 healthy elderly subjects and 12 young university students. In their previous work, experienced Tai Chi participants had better joint proprioception and balance control during weight shifting (Tsang & Hui-Chan, 2003). In this work, both experienced Tai Chi subjects and golfers had better knee proprioceptive acuity than the elderly control subjects. Both groups had faster reaction time, leaned further without losing stability, and exhibited better control of leaning trajectory than the elderly controls. Exercise, specifically Tai Chi, was shown to enhance the aforementioned variables. The latter two variables were also comparable to results in the younger cohort (Tsang & Hui-Chan, 2004). Improvement in variables such as reaction time, stability and leaning trajectory support the notion that exercise contributes favorably to the aging adult.

Due to the increased incidence of falls in the elderly, the Sensory Organization test is often utilized to quantitatively assess early alterations in visual, somatosensory and vestibular communication that contribute to fall risk. Tsang and Hui-Chan (2004) examined the effectiveness of a 4 and 8 week Tai Chi intervention in improving balance control in healthy elderly subjects. They evaluated 49 community-dwelling subjects (aged 69.1 ±SD 5.8 years) and volunteers either participated in supervised Tai Chi or general education for 1.5 hours, six times per week for 8 weeks. Two balance tests were administered using computerized dynamic posturography before, at 4 and 8 weeks during training, and at 4 weeks after training ended. The SOT included the six sensory conditions that could discern between visual, somatosensory and vestibular function and allow for body sway calculation changes. The LOS measured voluntary weight shift control in eight spatial positions while maintaining a stationary base of support. The outcome measures were compared between the two intervention groups, which included those experienced Tai Chi practitioners having means of 7.2 and 10.1 years of practice from two previous studies. After 4 and 8 week interventions, elderly subjects achieved significantly better vestibular ratio in the SOT and directional control in the LOS. The authors concluded that a 4 week Tai Chi training protocol is sufficient to improve balance control in the elderly subjects (Tsang & Hui-Chan, 2004).

The Step Up and Over test (SUO) simulates climbing stairs and negotiating curbs and other obstacles. This action is a critical element of gait in daily life. If an individual has balance and mobility problems, descending stairs can be one of the most challenging demands in their daily activities. Like gait, stair climbing/descending is a complex activity that can be altered by a large number of impairments. The SUO test is generally

considered to be a sensitive, but not specific, test of balance and mobility function. Due to the paucity of research in elderly females using this test, this research intervention will provide much needed data in the area of testing with the SUO test.

The Sit to Stand (STS) test simulates the act of rising from a seated to a standing position. This change in body position is influenced by a number of musculoskeletal, movement control, and balance factors. The individual's ability to accurately control center of gravity (COG) position is critical in controlling the rise movement, as well as in maintaining postural stability. If the COG is not maintained or positioned accurately either in the anterior or posterior position, the patient will either fall back into the chair or fall forward. The task also requires lateral stability. This aspect depends on symmetrical distribution of force between the two legs. Lastly, the ability to rise vertically also depends on adequate lower extremity and trunk strength, and range of motion. Movement or postural control impairments impact speed and COG position and control during the task. Functional consequences include the inability to rise from the seated position during performance of activities; rising from seats of variable heights; or a dependence on upper extremity assistance or the assistance of another person. Safety is a concern if instability occurs during or immediately following the rise, or while descending to sit. Schot, Knutzen, Poole & Mrotek (2003) performed an 8 week exercise intervention study that involved resistance training with 38 participants (14 men, 24 women; ages 60-90 years). They analyzed pre and post sit to stand performance and found significant improvements that were felt to be attributed to gains in strength. The peak forward, downward and upward velocity aspects of this functional movement increased with a delay in relative transition time. Their findings supported that resistance

exercise meaningfully improved function in a very important daily living activity (Schot et al., 2003).

With this data, quantitative assessment of functional capacity offers a unique contribution that is much needed in the literature. Functional capacity testing in the literature is lacking pre and post intervention with hydraulic resistance equipment. This study will contribute additional, much needed information in this area of literature. Due to the high incidence of falls and subsequent co-morbid conditions, functional capacity is a crucial variable to measure pre and post exercise intervention studies in the elderly.

Nutrition Intervention in the Elderly

A key component of weight management is sound dietary counseling and a consistent well-balanced diet. The appropriate percentage of macronutrients is also critical in balanced nutrition. Recommendations should include increased fruits and vegetables, decrease fat content to < 30% with < 10% from saturated fat, lean protein sources, protein intake for older men and women is between 1.0-1.25 g of high quality protein and appropriate percentages of macronutrients (Chernoff, 2006). This study will offer two nutrition plans; normal carbohydrate and high protein.

Successful aging involves the ability to maintain three key behaviors: decreased risk for disease and related disability, high mental and physical function, and active participation in life (American Dietetic Association, 2005). Nutrition is considered one of the major determinants in this process. One's nutrition choices are not only critical to one's physiological well-being, but also contribute to one's social, cultural and psychological quality of life. The most influential behaviors influencing aging aside

from genetics include consistently eating a healthy diet, being physically active, and avoiding tobacco (American Dietetic Association, 2005).

Normal aging is accelerated by variables that are associated with the concomitant frailty of the elderly adult. This age group has age-related decline in food intake as well as other complicating factors in achieving adequate nutrition such as poor dentition, financial resources and alterations in brain function that can all contribute to poor nutrition. One such factor, the decline in food intake has been termed the anorexia of aging. Many experts in the field of gerontology consider the decline in food intake to be an important factor in the development and progression of sarcopenia (Doherty, 2003). Sarcopenia is defined as a reduction in muscle mass and strength. Normal aging in humans progressively leads to the decline in neuromuscular function, ultimately affecting the ability to perform daily activities. Sarcopenia has also been coupled with the condition of obesity. The term used to describe this condition is called sarcopenic obesity. This combination of diseases produces the worst of both worlds in the elderly. The "fat frail" steadily become weaker leading to decreased mobility, functional capacity and are at higher risk for fall-related injury.

In elderly adults there are many variables that can affect sound nutritional habits. This age group can suffer from financial constraints and access to better food options. There has been extensive research in comparing various macronutrients combinations for health, weight reduction and maintenance in the adult population. The two areas that have gotten the most attention include high protein/low carbohydrate and normal carbohydrate/low protein diets. The Curves program offers both of these options. In

previous Curves research, both diets have produced weight loss in the short term during a 14 week intervention with exercise (Kreider, 2005).

Previous research has postulated that protein intake may be one of the causative factors in the complex equation of sarcopenic obesity. It is well documented that adequate protein intake is crucial in maintaining integrity, function and health of humans by contributing amino acids that serves as precursors for essential molecules that serve as building blocks for all cell components (FAO/WHO/UNO, 1985). It is also important to note that adequate intake of carbohydrates, fats, vitamins, minerals; fiber and water also need to be ingested in order for these processes to occur. High protein diets have also shown improvement in weight loss, maintaining muscle mass and improving blood markers in all ages. There is also a substantial amount of research that supports certain diagnoses may actually respond more favorably to high protein nutrition plans. The majority of nutritional research in weight loss and maintenance has been done on the adult population spanning from young adult (age 20) to the young old (aged 60). There is currently a paucity of research in the healthy elderly because nutritional research in this age group tends to be disease specific and primarily focused on institutionalized or hospitalized patients. Noakes, Keogh, Foster & Clifton (2005) performed a study comparing hypocaloric high protein (HP) diet to a high carbohydrate (HC) diet. Approximately 100 participants with a body mass index of 32 ± 6 and age of 49 ± 9 years completed the study. They were randomly assigned to one of two isocaloric 1337 kilocalorie (5600 kJ) dietary interventions for twelve weeks according to parallel design. Weight loss achieved was 7.3 ± 0.3 kg with both diets. The participants with high triacyglycerol lost more fat mass with the HP diet than with the HC diet (SEM= 6.4 ± .7

and 3.4 ± .7 kg, respectively) and had a greater decrease in triacyglycerol concentrations with the HP (~5.9 ± 0.19 mmol/L) that with the HC (~0.03 ± 0.04 mmol/L) diet. Fasting LDL-cholesterol, glucose, insulin, free fatty acid, and C-reactive protein concentrations decreased with weight loss. Serum vitamin B-12 increased 9% with both diets; homocysteine did not change significantly. Bone turn over markers increased 8-12% and calcium excretion decreased by 0.8 mmol/d. Creatinine clearance decreased from 82 ± 3.3 to 75 ± 3.0 mL/min. Their research supported the HP diet was effective in producing weight loss as well as improving risk factors for diabetes and heart disease (Noakes et al, 2005).

Meckling, O'Sullivan & Saari (2004) took a population of adult overweight and obese men and women (age 24-61) in a randomized study to compare the effects of a low-fat (LF) diet versus a low-carbohydrate diet (LC) diet intervention (retention 78%). The participants in the LF diet consumed approximately 17.8% of energy from fat, compared with their habitual intake of 36.4% and had a resulting energy restriction of 606 kcal/day (2540 kL/d). Participants on the LC diet consumed an average of 15.4% carbohydrate, compared with habitual intakes of about 50% carbohydrate, and had a resulting energy restriction of 763 kcal (3195 kJ/d). Significant weight loss was achieved in both groups over the ten week intervention and there were almost identical improvements in body weight and fat mass. LF participants lost an average of 15 pounds (6.8 kg) and had a decrease in body mass index of 2.2 kg/m^2, compared with a loss of 7.0 kg and a decrease in body mass index of 2.1 kg/m^2 in the LC participants. The LF group showed a better preserved lean body mass when compared with the LC group. However, the LC group showed a significant decrease in circulating insulin concentrations. Group

results indicated the diets were equally effective in reducing systolic blood pressure by about 10 mmHg and diastolic pressure by 5 mmHg. A decrease in plasminogen activator inhibitor-1 bioactivity was also seen in both groups. Blood β hydroxbutyrate (supporting adipose tissue utilization for energy) concentrations increased in the LC group only at the 2- and 4- week time points. These data suggest that energy restriction achieved by a very LC diet is equally effective as a LF diet strategy for weight loss and decreasing body fat in overweight and obese adults (Meckling, O'Sullivan & Saari 2004). Other benefits noted in literature for low carb/ high protein diets include: decreased central adiposity and reduction in cardiovascular disease rates (Noakes, et al., 2005). Visceral adiposity is of concern because it is felt to be more threatening possibly due to its position in the body and drainage via venous portal veins. It is important to note that long term studies need to be done in this area to confirm short duration studies. It has also been noted that low carbohydrate/high protein diets are not always well tolerated long term and safety in patients with altered renal function is unknown as well (Noakes et al., 2005).

Layman, Evans & Baum (2005) tested the benefits of high dietary protein, while maintaining the recommended macronutrient composition above. Their study included forty-eight overweight and obese women between the ages of 40-56 years to be in two diet groups with and without exercise. The higher-protein, reduced-carbohydrate diet (PRO) diet was designed to provide dietary protein at 1.6 g/kg per day (~30% of calories) and ~ 30% of calories from dietary fat, allowing a carbohydrate-protein ratio of <1.5. The higher-carbohydrate, moderate-protein diet (CHO diet) was designed to provide 0.8 g/kg per day of dietary protein (~15% of calories) and ~30% of calories from dietary fat, yielding a carbohydrate: protein ratio of >3.5. Both of the diet groups were within the

Boundaries of Acceptable Macronutrient Distribution Ranges (AMDR) defined by the Institute of Medicine. Each diet group was randomly assigned to participate in either supervised exercise or control, following the NIH guidelines of walking 30 minutes per day at least five days per week. They concluded that diets higher in protein and moderate in carbohydrate appear to have an advantageous for weight reduction, body composition, and plasma triacylglycerol. The high carbohydrate diet was shown to more efficiently decrease total and LDL cholesterol levels. The authors concluded that diets should consider clinical outcomes and pre-existing lipid values (Layman et al., 2005).

Based on research to date the high protein and normal carbohydrate diets both produce favorable weight loss in studies up to one year. There is evidence in short term studies that the high protein diet may offer more in regards to specific serum markers (e.g., lipids) and blood pressure but it is unknown how tolerable these diets are longer term. There is also concern regarding the effects low carbohydrate diets have on phytochemical composition and fiber. The safety of these diets for an extended period of time (e.g., > one year) in patients with altered renal function has also yet to be proven long term (Noakes et al., 2005). More research is needed in this area over a longer period of time to test compliance and tolerance of each diet as well as long term effects in specific areas such as blood markers, bone density, muscle mass and ability to maintain weight loss. The purpose of dietary intervention in this study is to compare previous success in younger age groups on Curves diets to the elderly female population and will specifically look at muscle mass alterations comparing the two diet groups to the exercise only group.

Quality of Life in the Elderly

Health Related Quality of Life (HRQOL) measures are being used with increased frequency in studying the affects of obesity (Spiker, 1996; Testa & Simonson, 1996). The SF-36 has been described as the most widely used HRQOL measure (Kolotkin & Crosby, 2002). This assessment tool was originally used to measure health outcomes in a 2-year observational study of more than 22,000 adult participants (Wadden & Phelan, 2002; Tarlov et al., 1989). It was modified in 1989 (Stewart, Greenfield, & Hays, 1989) and again in 1992 to its current format of a 36-item Short Form General Health Survey (SF-36) (Ware & Sherbourne, 1992). The assessment is based on participant perceptions over the past four weeks prior to assessment. Previous research has shown that obesity appears to impact physical health, emotional well-being and psychosocial functioning (Kawachi, 1999; National Institute of Health, National Heart, Lung, and Blood Institute, 1998; Pi-Sunyer, 1993; Rissanen, (1996). The reliability, validity and internal consistency of the eight areas measured by the SF-36 are illustrated in Table 3 below. The range of functioning capacity measured by the SF-36 is shown in Table 4.

Table 3. *Reliability and Validity of SF-36 Scales*

Scale	Internal Consistency	Test-retest Reliability	Validity
Physical Functioning	0.92	0.81	-0.63
Role Limitation (physical)	0.83	0.69	-0.46
Pain	0.81	0.78	-0.59
Social Function	0.85	0.60	-0.67
Role limitation (emotional)	0.83	0.63	0.38
General Health	0.79	0.80	0.45
Vitality	0.87	0.80	0.45
Mental health	0.90	0.75	0.60

Note: Source from Ware, J.E. (1993). SF-36 Survey. Manual and Interpretation Guide. Boston: Nimrod Press.

Table 4. *SF- 36 Conceptual Framework and Item Selection*

Concepts	No. of Items	Range of Functioning	
Physical Functioning	10	Limited a lot in performing all physical activities including bathing or dressing due to health	Performs all types of physical activities including the most vigorous without limitation due to health
Role-physical	4	Problems with work or other daily activities as a result of physical health	No problems with work or other daily activities as a result of physical health
Bodily pain	2	Very severe and extremely limiting pain	No pain or limitation due to pain
General health	5	Evaluates personal health as poor and believes it is likely to get worse	Evaluates personal health as excellent
Vitality	4	Feels tired and worn out all of the time	Feels full of pep and energy all of the time
Social functioning	2	Extreme and frequent interference with normal social activities due to physical or emotional problems	Performs normal social activities with out interference due to physical or emotional problems
Role-emotional	3	Problems with work or other daily activities as a result of emotional problems	No problems with work or other daily activities as a result of emotional problems
Mental health	5	Feelings of nervousness and depression all of the time	Table 4 cont.
Reported health transition	1	Believes general health is much worse now than one year ago	Feels peaceful, happy, and calm all of the time

Note: Source from Ware, J.E. & Sherbourne, C.D. (1992). The MOS 36-item short-form health survey (SF-36) I: *Medical Care*. 30, 473-83.

Previous HRQOL research shows that obese people seeking weight loss treatment are significantly more impaired than those who are not trying to lose weight (Fontaine, Bartlett & Barofsky, 2000). HRQOL varies with the degree of obesity, supporting those suffering from more severe obesity have the poorest quality of life (Fontaine, Cheskin & Barofsky, 1996).

Weight maintenance, regardless of baseline weight also affects HRQOL. Previous research has shown that a loss or gain of 2.5 kg can impact areas such as

physical functioning, vitality and bodily pain. Fine et al. (1999) took data from the Nurse's Health Study over a 4-year period of time in a prospective, observation study from 1992 to 1996. HRQOL was measured in a cohort of 40,098 women (ages 46-71 years old in 1992). They were grouped according to three patterns of weight change. The groups were established by women whose weight remained within 2.25 kg (5 lb) of their baseline weight, women who lost 2.5 kg or more and women who gained 2.25 kg or more. Score changes were monitored from seven health-related quality of life dimensions: physical functioning, vitality, bodily pain, limitations in role functioning due to emotional or physical problems, social functioning and mental health as measured by the SF-36 Survey. Their results showed that a total of 15,602 women (39%) maintained their weight, 15,160 (38%) gained between 2.5 and 9 kg (5-20 lb.) and 6667 (17%) lost between 2.25 and 9 kg (5-20 lb). Those in the weight gain group had decreased physical function and vitality, and increased bodily pain regardless of baseline weight. In contrast, the weight loss group had improved physical function and vitality as well as decreased physical pain. It was also noted that weight change was more strongly associated with physical versus mental health. The impact of weight change was equal for women over age 65 as compared to the women younger than age 65. The researchers concluded that all women, regardless of baseline weight should avoid weight gain. Weight maintenance plays a key role in HRQOL areas of physical function, vitality and controlling bodily pain (Fine et al., 1999).

Mood states have been shown to be a concern in the obese. Heightened levels of depression and other psychopathology have been described as common in men and women seeking weight loss treatment (Fitzgibbon, Stolley & Kirschenbaum, 1993;

McReynolds, 1983). The Beck's Depression Inventory-II (BDI-II) (Beck, Steer & Brown, 1996) includes 21 items that specific measure depression. Its internal consistency, test-retest reliability and validity have been proven (Beck, Steer & Brown, 1996). The survey is also time efficient, taking approximately five minutes to complete. This survey has also been shown to be specifically responsive to weight reduction (Wadden, Foster, & Letizia, 1994; Wing, et al., 1994) and cognitive interventions (Dobson, 1988).

The Profile of Mood States (POMS) is a valid and reliable tool used to assess mood changes post research intervention. Stewart et al. (2003) studied whether levels of fitness, habitual physical activity, and fatness are associated with HRQOL and mood in older persons. Their subjects included men (n=38) and women (n=44), ages 55 to 75 years, who aside from mild hypertension, were otherwise healthy individuals. The population had not previously engaged in regular exercise or diet intervention. The groups were assessed using maximal oxygen uptake via treadmill testing, muscle strength using one-repetition maximum, habitual activity by questionnaire, fatness via dual-energy x-ray absorptiometry and body mass index. HRQOL was assessed by using the Medical Outcomes Study SF-36 and mood by the Profile of Mood States (POMS). Bivariate and multivariate regressions were used to determine correlations. Their results showed that higher aerobic fitness was associated with more desirable outcomes, as indicated by the POMS anger and total mood disturbance scores and by the SF-36 bodily pain, physical functioning, vitality, and physical component scores. Less desirable outcomes were associated with increased fatness, in the categories of POMS anger, depression and total mood disturbance scores. Less desirable scores were also noted in the SF-36 bodily pain,

physical functioning, role-emotional, role physical, social functioning, vitality, and physical component scores. Higher physical activity was associated with increased POMS score for vigor and a decreased SF-36 score for bodily pain. Strength did not relate to any areas of the HRQOL or mood. The strongest predictor for POMS total mood disturbance and SF-36 score for vitality was aerobic fitness. Fatness was the strongest predictor of the POMS anger score and the SF-36 bodily pain, physical functioning and physical component scores. Stewart et al. (2003) concluded that even in the absence of regular exercise and diet, relatively small amounts of routine physical activity can produce a better HRQOL and mood. These changes were noted in those having slight increases in fitness and lower body fat.

The Body Image questionnaire will be performed for comparison of previous Curves® intervention studies. Research on senior aged adults has shown that a negative self image can have powerful psychological as well as physiological affects (Hausdorff, Levy & Wei, 1999). The negative images of aging in our media, portraying older people as institutionalized, in poor health, senile, etc., can lead to belief and internalization of such stereotypes (Hummert, 1990; Levy, 1996; Levy, 2000).

The Eating Satisfaction Survey will be utilized to maintain consistency among all Curves Intervention Studies to date. This tool was designed by Curves International and has not been proven valid or reliable however, this may be done in the future. Utilizing this tool merely satisfies the requirements of the study sponsor and is listed as a limitation of the study.

Conclusion

The elderly population is currently one of the fastest growing segments in our nation (Elia, 2001). Due to the high prevalence of obesity in this age group it has been estimated that almost one-third of health care expenditures is for older adults (over age 65) (Physical Activity and Older Americans: Benefits and Strategies, 2002). There is currently a limited amount of research in elderly nutrition intervention in non institutionalized, healthy populations. Hence, it has yet to be determined what the ideal macronutrient and caloric percentages are needed for this population. Current literature supports that there are risks associated with weight loss in this age group. There is debate on ideal weight for this population due to potential harmful effects of weight loss on muscle and bone mass, as well as the ideal amount of weight loss necessary to produce improved health. This study will provide much needed information regarding which Curves dietary program (HP and NCHO) is more effective in retaining muscle mass in elderly females. A decline in muscle mass alters daily energy expenditure, insulin sensitivity as well as functional related variables such as muscle weakness, fatigability and decline in endurance. In the group that has the best muscle mass retention, the impact on functional capacity measures will be determined via the NeuroCom SmartEquitest system. These results will provide additional data regarding whether functional capacity can be enhanced during weight loss in combination with maintained or enhanced muscle mass. This study will also compare and contrast results of the elderly population to younger cohorts previously studied.

CHAPTER THREE

Methods

Participants

Approximately 60 sedentary, overweight senior female participants (BMI > 27) between the ages 60 to 75 participated in this 14 week study. Participants were medically cleared by their physician and were not be allowed to participate in this study if they had any uncontrolled metabolic disorder, known electrolyte abnormalities, heart disease, arrhythmias, diabetes, or thyroid disease; a history of hypertension, hepatorenal, musculoskeletal, autoimmune, or neurological disease. If they were taking hypoglycemic, or androgenic medications; and/or, if they had taken ergogenic levels of nutritional supplements that may affect muscle mass (e.g., creatine, HMB), anabolic/catabolic hormone levels (e.g., DHEA), or weight loss (e.g., thermogenics) within three months prior to the start of the study. The only exception allowed was if the prospective participant had a medical condition or history that the participant's personal physician felt was controlled and therefore would not be a limitation for them to have participated in the study. Participants that met eligibility criteria were informed of the requirements of the study and signed consent statements in compliance with the Human Participants Guidelines of Baylor University and the American College of Sports Medicine. Participants were required to obtain clearance to participate in the study from their personal physician before participating in baseline assessments.

Study Site

All testing was conducted in the Exercise & Sport Nutrition Laboratory (ESNL) in the Department of Health, Human Performance, and Recreation at Baylor University. Exercise training was conducted at the Student Life Center at Baylor University.

Experimental Design

Table 5 below shows the general research design and time course for assessments. The independent variable was dietary intervention. Dependent variables included: estimated dietary energy intake; body composition, and body water assessment; hip and waist anthropometric measurements; resting energy expenditure (REE), fasting clinical blood profiles (liver enzymes, red cells, white cells, insulin, leptin, ghrelin, adiponectin, and ß-hydroxybutyrate); maximal cardiopulmonary exercise capacity; 6 minute walk test, isotonic strength; balance tests, standardized quality of life (SF-36), body image, and eating satisfaction inventories.

Entry and Familiarization Session

Participants who expressed interest in participating in this study were interviewed on the phone to determine whether they qualified to participate in this study. Participants felt to meet eligibility criteria were invited to attend an entry/familiarization session. During this session, Participants signed Informed Consent Statements and completed personal and medical histories. Participants were required to obtain medical clearance from their personal physician prior to participating in baseline assessments. Once medical clearance was obtained, participants were familiarized to the study protocol via a verbal and written explanation outlining the study design. This explanation included describing the training and dietary program, and familiarizing the participants to the tests

to be performed. Participants were given an appointment time to perform baseline assessments summarized in table 5.

Table 5. *Overview of Research Design and Testing Schedule*

Familiarization And Entry T1	Week 0 (T2)	Week 10 (T3)	Week 14 (T4)
Phone interview Familiarization session General exam to determine qualifications to participate in study General nutritional counseling Equitest familiarization	Day 1 Maximal Cardiopulmonary Test and ECG Day 2 Dietary history QOL/Eating Questionnaire Body mass Body water DEXA Body Composition Fasting blood Collection Resting Bp/ECG Resting Energy Expenditure Equitest 6 Minute Walk Test 1 RM Bench Press & Leg Press Participants matched according to FFM and age for random assignment Into: A. High Protein/Low Fat Diet I/Exercise B. High Carbohydrate/Low Fat Diet III/Exercise C. Exercise only-control Initiate Curves 30-minute Fitness Training Program	Dietary history QOL/Eating Questionnaire Body mass Body water DEXA Body Composition Fasting blood Collection Resting Bp/ECG Resting Energy Expenditure Equitest Snack 6 Minute Walk Test	Day 1 Maximal Cardiopulmonary Test and ECG Day 2 Dietary history QOL/Eating Questionnaire Body mass Body water DEXA Body Composition Fasting blood Collection Resting Bp/ECG R E Equitest 6 Minute Walk Test 1 RM Bench Press & Leg Press

Table Continues

Randomization and Dietary Intervention

Table 6 presents the exercise and dietary intervention protocol employed in the study. Participants were randomized into one of three groups based on the Curves for Women exercise and diet plan protocol (Heavin, 1999). The groups included: 1.) Exercise + Normal Carbohydrate/Low Protein Diet (NCHO) 2.) Exercise + Low Carbohydrate/ High Protein (HP) and 3.) No diet + exercise (E). Participants maintained the Phase I diet for one week along with exercise. Participants in the diet groups then followed a 9 week dietary intervention program according the protocol described in Table 6. Our previous research has shown that this 10-week program promotes a 10 – 15 lbs weight loss (Kreider, 2005). In the maintenance phase participants consumed a normal diet (Phase III) and if weight increases by 3 pounds requires they return to the Phase I (1,200 kcals/day) for 3-5 days until the weight was lost. Participants followed a diet plan prepared by a registered dietitian that adhered to the macronutrient intake as described in Table 6.

Training Protocol

All participants attended and performed the 30 minute Curves circuit three times per week for 14 weeks while maintaining a greater than 80% compliance record. The circuit involved 13 hydraulic resistance exercise machines involving bidirectional assistance working all major muscle groups interspersed with floor-based exercises designed to maintain an elevated heart rate. The Curves circuit is located on the third floor of the Student Life Center (SLC). Trained research assistants monitored exercise sessions, record attendance and instructed participants to complete a medical side effect report weekly.

Medical Monitoring

Interested participants were invited to familiarization sessions. During this time, participants signed consent forms and completed medical history information. Based on review of this information, a recommendation was made by a registered and certified family nurse practitioner on whether the participant met entry criteria in order to participate in the study. Participants who met entrance criteria were required to obtain a letter of medical clearance from their personal physician on the form provided by the study. This exam included evaluating the medical and training history questionnaires and performing a general physical examination according to ACSM exercise testing guidelines (ACSM, 2000). A physician and certified nurse practitioner were present for all baseline treadmill tests. A telephone and an automated electronic defibrillator were located in the laboratory in case of any emergencies and there were no less than two researchers working with each participant during testing sessions. In the event of any unlikely emergency one researcher would check for vital signs and began any necessary interventions while the other researcher contacts Baylor's campus police at extension 2222. Instructions for emergencies were posted above the phone in the event that any other research investigators were available for assistance. Participants were informed to report any unexpected problems or adverse events they encountered during the course of the study to Melyn Galbreath, MSN, FNP-C or Richard B. Kreider, PhD, EPC. If clinically significant side effects were reported, the participant was referred to their personal physician.

Testing Methods

Dietary Inventories. Following the familiarization/practice session, the participants would record all food consumption on dietary record forms for four days (4-d). Food logs were turned in at each test session. Dietary information was assessed by Food Processor III Nutrition Software (ESHA Nutrition Research, Salem, OR). Participants were randomized into two dietary groups and an exercise only group. The two groups included: high carbohydrate/low protein group (NCHO) and high protein/carbohydrate restricted diet (HP). They were instructed to follow a diet plan developed by a registered dietitian that followed the macronutrient intake described in Table 6 below.

Test Sessions. Participants were instructed to refrain from exercise for 48 hours and fast for 10-12 hours prior to baseline testing. Participants reported to the ESNL for body composition and clinical assessments. Once reporting to the lab, participants completed the SF-36 quality of life (QOL) inventory, a body image questionnaire, the Profile of Mood States (POMS) psychological inventory, the Beck Depression Inventory, an appetite/eating satisfaction questionnaire. Participants were weighed, had total body water determined by bioelectrical impedance (BIA), and body composition determined using a Discovery W Dual Energy X-ray Absorptiometry (DEXA). Participants then had hip and waist measurements determined. Following these assessments, participants underwent resting energy expenditure (REE) and blood pressure measurement per standard procedures. Participants donated approximately 20 ml of fasting blood using venipuncture techniques of an antecubital vein in the forearm according to standard procedures.

Table 6. *Dietary Intervention Program*

Diet Period	Group	Macro-nutrient	Gms/ Day	Kcals/ Day	Percentage of Daily Diet (%)
Phase I (One week)	HP + Exercise 1,200 kcals/day)	Protein	190	760	63
		Carbohydrate	20	80	7
	(n=20)	Fat	40	360	30
	NCHO + Exercise (1,200 kcals/day) (n=20)	Protein	45	180	15
		Carbohydrate	165	660	55
		Fat	40	360	30
	Exercise only (E) (ND) Control (n=20)				
Phase II (Nine Weeks)	HP + Exercise 1,600 kcals/day) Any intake (n=20)	Protein	220	880	55
		Carbohydrate	60	240	15
		Fat	40	360	30
	NCHO + Exercise 1,600 kcals/day) (n=20)	Protein	60	240	15
		Carbohydrate	220	880	55
		Fat	40	360	30
	Exercise only (E) Control (n=20)				
Maintenance Phase (Four Weeks) 2100 calories daily in each diet group unless weight gain of 3 lb.s Participant will reduce to 1200 calories for 3-6 days until additional weight is reduced	HP + Exercise 2,100 kcals/day) (n=20)	Protein			
		Carbohydrate			
		Fat			
	NCHO + Exercise 2,100 kcals/day) (n=20)	Protein			
		Carbohydrate			
		Fat			
	Exercise only (E) Control (n=20)				

Blood samples were in the EBNL for clinical chemistry profiles (glucose, total protein, blood urea nitrogen, creatinine kinase, BUN/creatinine ratio, liver enzyme panel, albumin, calcium, total bilirubin, alkaline phosphatase, triglycerides, cholesterol, HDL, LDL) and whole blood cell counts with differential (including hemoglobin, hematocrit, red blood cell counts with indices, white blood cell counts, neutrophils, lymphocytes, monocytes, eosinophils, baosphils). In addition, serum samples will be assayed for insulin, leptin, adiponectin, ghrelin, and ketones (β hydroxybutyrate). Participants were tested via Equitest Smart System in four balance tests that include: Sensory Organization Test (SOT), Limits of Stability (LOS), Step Up and Over (SUO) and Sit to Stand (STS). Participants then performed 1 repetition maximum lifts on the bench press and leg press to assess strength as well as endurance testing. The participant would perform as many repetitions as possible with 80% of their 1 RM efforts for upper and lower body testing. Finally, participants performed a 6 minute walk test, maximal cardiopulmonary exercise stress test to assess aerobic capacity and anaerobic threshold.

Psychometric Assessments. Participants completed the SF-36 Quality of life (QOL) inventory (Ware et al., 1995), the Profile of Mood States (POMS) psychological inventory, the Beck Depression Inventory and an appetite/eating satisfaction questionnaire. Validity and reliability of these tools are detailed in the previous chapter. Following the study, participants were asked to complete a post-study questionnaire to assess impressions about the Curves fitness and weight loss program.

Body Composition Assessments. Participants underwent body composition tests in the ESNL. Prior to each assessment, height was measured using standard anthropometry and total body weight was measured using a calibrated electronic scale

with a precision of +/-0.02 kg. Total body water was estimated using a Xitron 4200 Bioelectrical Impedance Analyzer (San Diego, CA) which measures bio-resistance of water and body tissues based on a minute low energy, high frequency current (500 micro-amps at a frequency of 50 kHz) transmitted through the body. This analyzer is commercially available and has been used in the health care/fitness industry as a means to assess body composition and body water for over 20 years. The use of this device has been approved by the Food and Drug Administration (FDA) to assess total body water and the current to be used has been deemed safe. This is measured through four electrodes placed on the body: one electrode will be placed on the posterior surface of the right wrist, in between the radial and ulna styloid processes (wrist bones), another electrode was placed on the posterior surface of the right hand at the distal base of the second metacarpal; the third electrode was placed on the anterior surface of the right foot at the distal end of the first metatarsal. Participants were in a supine position on an exam table and electrodes were connected to the analyzer. After the participant was connected, age, gender, weight, height, and activity level were entered into the unit by the technician. After the unit measured the resistance, which takes approximately 30 seconds, the unit then calculates total body water and body water percent. Bioelectric impedance analysis has been determined to be a valid measurement for total body water (Van Loan, 1990). Body composition/bone density was determined using a calibrated Discovery W dual energy x-ray absorptiometry (DEXA) by qualified personnel with limited x-ray technology training under the supervision of Richard B. Kreider, PhD, MX. Quality control (QC) calibration procedures were performed on a spine phantom (Discovery W-CALIBER Model DPA/QDR-1 anthropometric spine phantom) prior to

each testing session. In addition, weekly calibration procedures were performed on a density step calibration phantom. The DEXA body composition test involved having the participant lie down on their back in a standardized position in a pair of shorts/t-shirt or a gown. A low dose of radiation scanned their entire body for approximately six (6) minutes. The DEXA segments regions of the body (right arm, left arm, trunk, right leg, and left leg) into three compartments for determination of fat, soft tissue (muscle), and bone mass. Radiation exposure from DEXA for the whole body scan is approximately 1.5mR per scan. This is similar to the amount of natural background radiation a person would receive in one month while living in Waco. The maximal permissible x-ray dose for non-occupational exposure is 500 mR per year. Total radiation dose was estimated to be less than 5mR for the entire study. Test-retest reliability studies performed on male athletes with this DEXA machine yielded mean deviation for total BMC and total fat free/soft tissue mass of 0.31% with a mean intra-class correlation of 0.985.

Resting Heart Rate & Blood Pressure. Heart rate was determined by palpitation of the radial artery using standard procedures (ACSM, 2000). Blood pressure was assessed in the supine position after resting for 5-min using a mercurial sphygmomanometer using standard procedures (ACSM, 2000).

Blood Samples. Participants fasted overnight for 10-12 hours and donated approximately 4 teaspoons of fasting venous blood (20 milliliters). Blood samples were obtained using standard phlebotomy procedures using standard sterile venipuncture of an antecubital vein by laboratory technician's trained in phlebotomy in compliance with guidelines established by the Texas Department of Health and Human Services. The phlebotomists and lab technicians wore personal protective clothing (gloves, lab coats,

etc.) when handling blood samples. Participants were seated in a phlebotomy chair. Their arm was cleaned with a sterile alcohol wipe and sterile gauze. A standard rubber tourniquet was placed on the brachium. An antecubital vein was palpated and then a 23 gauge sterile needle attached to a plastic vacutainer holder was inserted into the vein using standard procedures. Three serum separation vacutainer tubes (red tops) and one EDTA vacutainer tubes (purple top) were inserted into the vacutainer holder for blood collection in succession using multiple sample phlebotomy techniques. Once samples were obtained, the vacutainer holder and needle were removed. The needle was discarded as hazardous waste in a plastic sharps container. The site of the blood draw was cleaned with a sterile alcohol wipe and gauze and a sterile Band-Aid was placed on the site. The blood collection tubes were labeled and placed in a test tube rack. Laboratory technicians (who have received blood borne pathogen training and were wearing personal protective clothing) centrifuged the serum samples, transferred the serum into labeled serum storage containers, and prepared samples for storage into a refrigerator or freezer for subsequent analysis. Serum and whole blood samples were analyzed in the EBNL for assay of a standard clinical chemistry profile (glucose, total protein, blood urea nitrogen, albumin, creatinine kinase, BUN/creatinine ratio, aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma-glutamyl transferase (GGT), total bilirubin, alkaline phosphatase, triglycerides, cholesterol, high density lipoprotein (HDL), low density lipoprotein (LDL). Whole blood cell counts (including hemoglobin, hematocrit, red blood cell counts, white blood cell counts, neutrophils, lymphocytes, monocytes, eosinophils, basophils) were assessed during the 14 week intervention. Serum microcentrifuge samples were assayed for insulin, leptin,

adiponectin and ghrelin using standard ELISA and spectrophotometric techniques in the EBNL at Baylor University. Ketones/ β-hydroxybutyrate (ß-HBA) were analyzed via the DADE using a reagent. This quantitative measure is considered a kinetic enzymatic method to measure ketone levels in serum or plasma. The method is based on the oxidation of D-3-hydroxybutyrate to acetoacetate by the enzyme 3-Hydroxybutyrate dehydrogenase. Concomitant with this oxidation the cofactor NAD+ is reduced to NADH and the associated change of absorbance can be directly correlated with the D-3-hydroxybutyrate concentration. The result was read at 340 nm. The analysis of these blood parameters was performed to determine the exercise and dietary intervention on general markers of clinical health status, insulin, and markers of fat oxidation/regulation. The DADE Dimension RXL clinical chemistry analyzer (Dade-Behring, Inc., Newark, DE), and an Abbott Cell Dyn 3500 hematology analyzer (Abbott Laboratories, Chicago, IL) were used for the standard chemistry profile and Complete Blood Count analysis respectively. Test to test reliability (within and between) of performing these assays ranged from 2 to 6% for individual assays with an average variation of ± 3%. Samples were run in duplicate to verify results if the observed values were outside control values and/or clinical norms according to standard procedures.

Serum leptin was determined by an enzyme linked immuno-absorbent assay (ELISA) (Cayman Chemical, AnnArbor, MI; Diagnostic Systems Laboratories, Webster, TX). The principle of the following enzyme immunoassay test follows a typical two-step capture or 'sandwich' type assay. This involves the use of ELISA kits that are coated into the wells of the microtiter strips with monoclonal antibodies specific for each hormone. The assay makes use of two highly specific monoclonal antibodies: A

monoclonal antibody specific for leptin is immobilized onto the microwell plate and another monoclonal antibody specific for a different epitope of leptin is conjugated to biotin. In the assay, samples, known standards, controls and unknowns are pipetted into the wells and incubated for binding to the antibody. After incubation and washing, a biotinylated monoclonal antibody specific for each hormone was added and then incubated again for additional binding. The excess second antibody was washed and the wells incubated with streptavidin-peroxidase enzyme which binds to the biotinylated antibody for completion of the four-layer sandwich. The streptavidin-peroxidase enzyme was washed to remove any unbound enzyme, and a substrate solution (Tetramethybenzidine solution) was added specific for each hormone. This solution was acted upon by the bound enzyme and color will be produced. The degree and intensity of the color produced indicates the concentration of leptin present. An acidic stopping solution (0.2 M sulfuric acid) was added and the degree of enzymatic turnover of the substrate determined by using a Wallac Victor-1420 microplate reader (Perkin-Elmer Life Sciences, Boston, MA). The assays were performed at a dual wavelength absorbance at 450 nm. A set of standards were used to plot a standard curve from which the amount of leptin in patient samples and controls were read. The estimated intra-assay coefficient of variation for this analysis was 3.8% and the inter-assay coefficient of variation was 4.4% (Diagnostic Systems Laboratory). The intra-assay coefficient of variation for this study was 2.7-9.1%.

Insulin was analyzed via an Enzyme Linked Immunosorbent (ELISA) Kit manufactured by Diagnostic Systems Laboratory (Webster, TX). The Insulin ELISA is an enzymatically amplified “one step” sandwich type assay. Serum samples are

incubated with another anti-insulin antibody. After incubation and washing, the wells were incubated with the substrate tetramethylbenzidine (TMB). To prepare the Insulin-Antibody-Enzyme Conjugate Solution the Insulin Antibody-Enzyme conjugate Concentrate was diluted in the Assay Buffer per instruction packet steps. The solution was added to each well using a semi-automatic dispenser. The wells were incubated by being shaken at a fast speed on an orbital microplate shaker at room temperature. Each well was washed five times and blotted dry. TMB chromagen solution was added to each well. The wells were incubated again via the orbital microplate shaker at room temperature while avoiding direct sunlight. A stopping solution (0.2 M Sulfuric acid) was added to each well using a semi-automatic dispenser. The absorbance of the solution in the wells was read within 30 minutes. The degree of enzymatic turnover of the substrate was determined by dual wavelength absorbance measurement at 450 and 620 nm. The absorbance measured is directly proportional to the concentration of insulin present. A set of insulin standards is used to plot a standard curve of absorbance versus insulin concentration from which the insulin concentrations in the unknowns can be calculated. The estimated intra-assay coefficient of variation for this analysis was 2.0% and inter-assay coefficient of variation was 5.7% (Diagnostic Systems Laboratory). The intra-assay coefficient of variation for this study was 5.5-7.5%. Homeostasis Model Assessment for insulin resistance (HOMA-IR) was calculated using fasting insulin and glucose values by the following formula: Insulin (uIU/mL) · glucose (mg/dL) / 405 (Sekiguchi, 2004). Low values support high insulin sensitivity and high values support low insulin sensitivity (Diagnostic Systems Laboratory).

The Human Ghrelin (Total) ELISA is an enzymatically amplified "one-step" sandwich-type immunoassay. In the assay, Standards, Controls, and unknown samples are incubated with anti-ghrelin antibody in microtitration wells, which have been coated with another anti-ghrelin antibody. After incubation and washing, the wells are incubated with the substrate tetramethylbenzidine (TMB). An acidic stopping solution (0.3 M HCL) was added and the degree of enzymatic turnover of the substrate was determined by duel wavelength absorbance measurement at 450 and 620 nm. The absorbance measured was directly proportional to the concentration of total ghrelin present. A set of total ghrelin standards was used to plot a standard curve of absorbance versus total ghrelin concentration from which the total ghrelin concentrations in the unknowns can be calculated. The predicted intra-assay coefficient of variation for this analysis is 7.9% (Diagnostic Systems Laboratory). The intra-assay coefficient for this study was 7.1-11.1%.

The Adiponectin kit is an enzyme-linked ELISA for qualitative determination of adiponectin in human plasma and serum. Standard, sample and diluted solutions were pipetted into the appropriate wells using a new tip for each sample solution. Plate was incubated at 37 degrees Celsius for one hour. The plate was decanted and wells washed three times with a wash solution. A secondary antibody (HRP labeled antibody) was added to each well and incubated again per protocol above. The wash step was repeated per above. A detector solution was added to each well and incubated at room temperature for twenty minutes. The stop solution was added and the plate was read at 450 nm. The absorbance of the blank was subtracted from the readings from each standard and sample. The standard curve was plotted with the known concentration of

the standard versus the absorbance of the standard. The adiponectin concentrations were calculated by interpolation of the regression curve formula. The serum dilution factor was multiplied to calculate adiponectin concentration of unknowns. The intra-assay coefficient of variation for this analysis is 3.9% (Diagnostic Systems Laboratory). For this study the intra-assay coefficient of variation was 3.2-13.2%.

Resting Energy Expenditure Assessment. Resting energy expenditure assessments were done according to standard protocols using the Parvo Medics TrueMax 2400 Metabolic Measurement System (Sandy, UT). This involved the participants lying down on an exam table and placing a see through metabolic canopy over the participant's neck and head so that metabolic measurements were obtained. The participant was motionless without going to sleep for 15-minutes. Metabolic measurements were obtained to determine resting oxygen uptake and energy expenditure. Test-to-test reliability yielded the following intraclass values: VE/O_2 = 0.95, 5.3%; RER = 0.87, 9.8%; VE/VCO_2 = 0.87, 12.1%; Max VTW = 0.98, 2.6% (Amann, et al., 2004).

Cardiopulmonary Exercise Tests. Cardiopulmonary exercise tests were performed by lab exercise physiology graduate students in accordance to standard procedures described by the American College of Sports Medicine's (ACSM) *Guidelines for Exercise Testing and Prescription.* This involved preparing the participant's skin for placement of 10 ECG electrodes. Electrode sites were cleansed with sterile alcohol gauze using a circular motion. The site was allowed to air dry or will be dried with a gauze pad. Electrodes were then be placed on the right subclavicular fossa (RA), left subclavicular fossa (LA), right abdomen (RL), left abdomen (LL), 4^{th} intercostals space at the right sternal border (V1), 4^{th} intercostals space at the left sternal border (V2), equidistant

between V2 and V4 (V3), 5th intercostal space at the midclavicular line (V4), 5th intercostal space at the anterior axillary line (V5), and 5th intercostals space at the axillary line (V6) of the chest. The participant was then attached to a Quinton 710 ECG. Resting blood pressure, heart rate, and a 12-lead ECG were obtained. A nurse practitioner reviewed the 12-lead ECG to ensure that no contraindications for exercise testing are apparent based on the ACSM guidelines. Participants were asked to stand on the treadmill. A sterile mouthpiece attached to a head harness was secured on the participant. The participant had a noseclip placed on their nose. Resting expired gases were collected using the Parvo Medics 2400 TrueMax Metabolic Measurement System. Once the participant was ready to begin the test protocol, the participant straddled the treadmill with both legs while the treadmill was turned on at a speed of 1.7 mph and at a 0% grade. The participant used one foot to repeatedly swipe the belt in order to gauge the speed of the motion. Once the participant was familiar with this speed, the participant stepped onto the belt while still gripping the handrail with both hands. Once the participant became comfortable walking on the treadmill, they let go of the handrail and began walking freely. The participant performed a standard symptom-limited Modified Bruce treadmill maximal exercise test using the following speeds and grades in Table 7:

The participant was encouraged to exercise to their maximum unless the participant experienced clinical signs to terminate the exercise test as stated by the ACSM's *Guidelines for Exercise Testing and Prescription* (i.e., angina, dyspnea, dizziness, a decline in systolic blood pressure, dangerous dysrhythmias [increasing or multi-form premature ventricular contractions, ventricular tachycardia, supraventricular tachycardia, new atrial fibrillation, or A-V block], lightheadedness, confusion, ataxia,

cyanosis, nausea, excessive rise in systolic blood pressure over 250 mmHg or diastolic over 120 mmHg, chronotropic impairment, failure of the monitoring system, or other signs or symptoms for terminating the test).

Table 7. *Modified Bruce Protocol*

Stage	Speed	Grade (%)	Duration
1	1.7	0	3
2	1.7	5	3
3	1.7	10	3
4	2.5	12	3
5	3.4	14	3
6	4.2	16	3
7	5.0	18	3

The test was terminated at the request of the participant. Once the exercise test was complete, the participant was observed for a 3 minute active recovery period followed by a 3 minute seated recovery period. The normal exercise time to maximum of the Modified Bruce treadmill protocol for untrained women is typically about 9-12 minutes (near the completion of stage III or just entering stage IV). Heart rate (HR), ECG tracings, and expired gases were monitored continuously throughout the exercise test. Blood pressure (BP) and ratings of perceived exertion (RPE) were obtained toward the end of each stage. Participants were asked to report any unusual signs or symptoms to the exercise specialists during the exercise test. This test determined maximal aerobic capacity and anaerobic threshold to discern the effects of exercise training on fitness and exercise capacity. The mean coefficient of variation (assessing Vo_{2max}) for this protocol is 6.5% (range 2-14%).

The Six Minute Walk Test (6MWT). The 6MWT was conducted using a standardized protocol utilizing a flat surface of 100-foot distance marked by colored tape on the gym floor. Participants were told to walk as far as possible for six minutes without running or jogging. Participants were instructed that they could stop and rest during the test but must resume walking as soon as they were able to do so. The tester used a mechanical lap counter to count the number of laps completed. A voice command was given with 10 seconds prior to the six minute limit. Testing was performed in the Marrs Mclean Gym. The test-retest reliability for the 6MW test was found to be .95-.97 (Steffen, Hacker & Mollinger, 2002).

Isotonic Strength Tests. All strength/exercise tests were supervised by certified lab assistants experienced in conducting strength/anaerobic exercise tests using standard procedures. Strength testing involved the participants performing one repetition maximum (1 RM) on the isotonic bench press and the Nebula Fitness (Versailles, OH) Olympic Power Station (#1005). Participants performed a warm-up (1 set of 8 – 10 repetitions at approximately 50% of anticipated maximum) on the bench press. Participants performed successive 1 RM lifts starting at about 70% of anticipated 1RM and increasing by 5 – 10 lbs until the participant reached their 1RM. Participants rested for 10 minutes and warm-up on the Nebula 45° Leg press (1 set of 8 – 10 repetitions at approximately 50% of anticipated maximum). Participants performed successive 1RM lifts on the leg press starting at about 70% of anticipated 1RM and increasing by 10 – 25 lbs until they reached 1RM. Test to test reliability of performing these strength tests on resistance-trained subjects in the ESNL have yielded low mean coefficients of variation and high reliability for the bench press (1.9%, intraclass $r = 0.94$).

Anthropometric Assessment. Hip and waist measures will be performed per guidelines established by the American College of Sports Medicine (2000). Hip and waist circumference are used to establish a ratio that has been shown to be a predictor of heart disease (Schneider et al., 2006).

Equi-Test Procedures. Functional capacity data were collected utilizing the Neurocom SmartEquitest® (Neurocom International, Portland, OR). The SmartEquitest® consisted of a long static force plate which measures balance and mobility and a Dynamic measuring balance and equilibrium. Test-to-test reliability in women aged 65-75 has been reported to be r=0.92 (Carter, et al., 2002). The Equi-Test testing session lasted approximately 20 minutes. Data was collected on postural balance and mobility utilizing the following tests in order:

Sit to Stand (STS): The STS test quantifies the patient's ability to rise from a seated to a standing position. The participant sat on a platform placed on a stationary force plate with the knees at 90 deg. of flexion. The participant was asked to rise from the seated position to a static standing position. There were 3 trials of the STS test.

Forward Step Up and Over (SUO): On a stationary force plate, the participant was instructed to step forward up on to a stable wooden box with their right leg, lift the left foot over the box and down onto the force plate back to an upright standing position. The test consisted of three trials of each side. The height of the step (8" or 12") was determined based on the participant's height and knee position. If the participant's knee flexion position exceeded 90 degrees when their foot is placed on the box, the appropriate size (4-12" box) was used to maintain 90 degrees flexion.

Limits of Stability (LOS): The LOS test was conducted on a stationary dual forceplate. The LOS quantifies the maximum distance a person can intentionally displace their center of gravity (COG), i.e., lean their body in a given direction without losing balance, stepping, or reaching for assistance. For each of 8 trials, the participant maintained their COG centered over the base of support as indicated by a cursor display on the of the COG position relative to a center target. On command, the participant moved the COG cursor as quickly and accurately as possible to a second target located on the LOS perimeter and then held the position. The participant was allowed up to 8 seconds to complete each trial for a maximum test time of 64 seconds.

Sensory Organization Test (SOT): The SOT consists of a sequence of 6 conditions of 3 trials lasting 20 sec. each.

Condition 1: Participant stood on a fixed forceplate with eyes open.

Condition 2: Participant stood on a fixed forceplate with eyes closed.

Condition 3: Participant stood on a fixed forceplate with eyes open while the visual surround moves in a 1:1 ratio to the participants' degree and direction of sway in order to disturb their visual field.

Condition 4: Participant stood with eyes open while the forceplate tilts anterior/posterior in a 1:1 ratio to the participant's degree and direction of sway.

Condition 5: Participant stood with eyes closed while the forceplate tilts anterior/posterior in a 1:1 ratio to the participant's degree and direction of sway.

Condition 6: Participant stood with eyes open while the forceplate tilts anterior/posterior in a 1:1 ratio to the participant's degree and direction of sway and the visual surround moves in a 1:1 ratio to the participants' degree and direction of sway.

Statistical Analysis. An Analysis of variance (ANOVA) for group x time repeated measures was used to analyze data with SPSS for Windows Version 14 software (SPSS Inc., Chicago, IL.). One-way ANOVA revealed that there were no statistically significant differences of baseline values between these variables. Data was considered statistically significant when the probability of type I error is 0.05 or less. A small effect size was defined as = 0.10, medium effect size= 0.25 and large is defined as = 0.40 (Kirk, 1999). A power of 0.80 is considered large (Kirk, 1999). Results are displayed with a degree of freedom (Df) equal to 1 for all variables and ηp^2 is Partial eta squared. All data are represented as means (± SD). Significant group, time and/or group x time interactions are depicted with an asterisk. If a significant group, treatment and/or interaction alpha level was observed, least significant differences (LSD) post-hoc analyses was performed to determine where significance was obtained.

CHAPTER FOUR

Results

The Curves Senior weight loss intervention study included 55 volunteers that completed the 14 week intervention. There were 73 participants recruited initially with 18 dropped enrollees. There were 15 participants who dropped within the first month of the intervention citing a lack of desire to continue, 1 participant cited recurrent musculoskeletal complaints unrelated to the intervention and dropped during the second month, 1 participant was medically dropped during the last week of the study due to recurrent symptoms of hypotension and 1 participant was dropped due to failure to comply with dietary instructions. All participants signed informed consent statements that were in compliance with the Institutional Review Board at Baylor University. Participant groups were matched by age, body weight and Body Mass Index and randomized into three groups. All 55 participants completed a 14 week exercise and/or weight loss intervention that included 3 test sessions. There were 17 participants in the high protein (HP) group and 20 participants in the Normal Carbohydrate (NCHO) and 18 participants in the Exercise (E) only group. Univariate ANOVA was utilized to illustrate there were no baseline differences between groups.

Demographics

Table 8 delineates the mean age, weight, height, body mass index and body fat for all participants. The recruitment age was between 60-75 years old. One-way ANOVA

revealed that there were no statistically significant differences of baseline values between these variables.

Table 8. *Group Demographics*

Variable	HP	NCHO	E	P Value
Age (years)	65.47 ± 5.2	65.90 ± 4.7	66.17 ± 4.3	.909
T1 Weight (kg)	81.69 ± 11.4	79.32 ±10.9	76.20 ± 9.8	.321
T1 Height (cm)	161.74 ± 6.8	161.54 ± 5.1	159.67 ± 3.8	.441
T1 BMI	31.26 ± 4.2	30.40 ± 3.8	29.95 ± 4.2	.628
T1 Body fat (%)	43.57 ± 3.74	44.23 ± 3.5	42.72 ± 3.8	.452

Note: All data represented as means ±SD. N=55. HP(n=17), NCHO (n=20) E (n=18)

Nutritional Intervention Groups

Dietary Summary. Table 9 shows the total caloric and macronutrient summaries at baseline (T1), 10 weeks (test session two = T2) and 14 weeks (test session three = T3) during the study intervention. The high protein group (HP) was given a dietary plan that consisted of 55-63% protein, 20% carbohydrate and 30% fat. The normal carbohydrate group (NCHO) was asked to follow a diet that included 55% carbohydrates, 20% protein and 30% fat. Both diet intervention groups were on a 1,200 calorie diet for the first week, 1,600 calories for weeks 2-9, and 2,100 calories for the remaining 4 weeks (maintenance phase). The HP group resumed the same macronutrient break down for the maintenance phase which was consistent with the NCHO group. The exercise only group was instructed to make no changes in their dietary patterns. The mean protein values below showed statistical significance in group main effect (p=0.000), time main effect

($p<0.003$), and group x time interaction ($p=0.001$). LSD post hoc analysis revealed differences between HP time 2 and NCHO time 2 ($p<0.05$). The mean normal carbohydrate values had statistically significant results in time main effect ($p<0.024$) and group x time interaction ($p=0.001$). LSD post hoc analysis revealed differences between HP time 2 and NCHO time 1, E time 1 and time 2 ($p<0.05$). These results indicate that the dietary intervention was successful in promoting significant differences between diet groups in carbohydrate and protein intake.

Body Composition

Body Mass. Table 10 presents body weight data observed among groups over the course of the study. There was a statistically significant time main effect ($p<0.001$) and group x time interaction ($p=0.002$). The group weight loss values in kilograms from baseline to the final test session were as follows: HP -3.9 ±10.7 kg, NCHO -2.3 ± 10.7 kg ±, E -.94 ± 10.7 kg. Post hoc analysis showed differences between HP time 1 as compared to NCHO time 2 and 3 ($p<0.05$). A significant difference in means was also noted between the aforementioned time points and all three time points for the E group. Weight mean percent changes between groups are as follows: HP -4.8 ± 3.2%, NCHO -3.0 ± 2.9%, E -1.1 ± 2.3%. The overall mean percent change in weight was -2.9 ± 3.1%.

Fat Mass. Table 11 summarizes body composition changes measured via (DEXA) during the study intervention. For fat mass, there was a statistically significant time main effect ($p<0.001$) and a significant group x time interaction ($p<0.001$). LSD post-hoc analysis revealed differences between HP group time 1 and 3 and between HP time 1 and E time 2 and time 3 ($p< 0.05$). For body fat percentage change, there was a

significant time main effect ($p<0.001$) and a significant group x time interaction ($p<0.001$).

Table 9. *Dietary Summary*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Calories (Kcals/d)	HP	1,598 ±415	1,567 ±292	1,712 ±352	Group	.023*	4.07	.140	.698
	NCHO	1,409 ±397	1,286 ±299	1,318 ±365	Time	.755	.282	.011	.092
	E	1,537 ±408	1,559 ±400	1,446 ±461	G x T	.141	1.77	.067	.523
	Time Mean	1,515 ±407	1,471 ±330	1,492 ±393					
Protein (g/d)	HP	66 ±13	95$^{\eta}$ ±31	86 ±18	Group	.000*	22.47	.473	1.00
	NCHO	58 ±13	56$^{\Psi}$ ±10	63 ±16	Time	.003*	6.71	.215	.899
	E	69 ±14	74 ±11	67 ±17	G x T	.001*	4.96	.168	.953
	Time Mean	64^{2,3} ±13	75^{1} ±17	72^{1} ± 17					
Carbs. (g/d)	HP	203†‡$^{\eta}$ ±56	146 ±44	193 ±67	Group	.827	.191	.008	.078
	NCHO	180$^{\Psi}$ ±68	171 ±56	168 ±51	Time	.024*	4.03	.141	.693
	E	192$^{\Psi}$ ±71	182$^{\Psi}$ ±61	173 ±62	G x T	.037*	2.66	.098	.723
	Time Mean	181^{2,3} ±65	173^{1} ±54	182^{1} ±60					
Total Fat (g/d)	HP	59 ±20	66 ±19	67 ±22	Group	.003*	6.36	.203	.883
	NCHO	51 ±15	44 ±11	46 ±17	Time	.630	.467	.019	.122
	E	56 ±16	63 ±23	57 ±23	G x T	.124	1.86	.070	.545
	Time Mean	55 ±17	58 ±18	57 ±21					

Note: Data represents nutritional summary at each test session during the 14 week intervention. LSD post hoc analysis is indicated by the following superscripts: Ψ= represents $p< 0.05$ difference from mean HP T2; η= represents $p< 0.05$ difference from mean NCHO T1. Post hoc follow up for time main effects are indicated numerically ($p<0.05$); 1= represents $p< 0.05$ difference from baseline mean; 2= represents $p< 0.05$ difference from mean T2; 3= represents $p< 0.05$ difference from mean T3.

Table 10. *Body Mass*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Body Weight (kg)	HP	$81.7^{\beta\mu\dagger\ddagger\Gamma}$ ±11.4	77.6 ±10.8	77.8 ±11.2	Group	.647	.44	.02	.12
	NCHO	79.6 ±10.9	77.4^{Ω} ±11.2	77.3^{Ω} ±11.6	Time	.000*	32.58	.56	1.00
	E	76.1^{Ω} ±9.8	75.2^{Ω} ±9.9	75.1^{Ω} ±10.3	G x T	.002*	4.72	.16	.94
	Time Mean	$79.1^{2,3}$ ±10.7	76.7^{1} ±10.6	76.7^{1} ±11.0					

Note: Data above represents body weight for the study. LSD post hoc analysis is indicated by the following superscripts: Ω= represents p< 0.05 difference from mean HP T1; β= represents p< 0.05 difference from mean NCHO T2; μ= represents p< 0.05 difference from mean NCHO T3; †= represents p< 0.05 difference from mean E T1; ‡= represents p< 0.05 difference from mean E T2; Γ= represents p< 0.05 difference from mean E T3; LSD post hoc analysis for time main effects is indicated numerically (p< 0.05); 1= represents p< 0.05 difference from mean T1; 2= represents p< 0.05 difference from mean T2; 3= represents p< 0.05 difference from mean T3.

Results of LSD Post hoc analysis for body fat percentage showed differences between HP time 1 as compared to NCHO time 2 and 3 (p< 0.05). The aforementioned weight loss was also achieved by maintaining muscle mass. It is worthy to mention that although no statistically significant differences were observed, muscle mass increased across groups.

The overall mean percent changes for fat mass were as follows: HP -10.2 ± 5.9%, NCHO -5.7 ± 4.0% and E -2.7 ± 3.9%. The overall mean percent change was -6.1 ± 5.5%. The mean percent changes in body fat percentage for each group were as follows: HP -6.3 ± 3.5%, NCHO -3.8 ± 3.4%, E -2.2 ± 3.6%. The overall mean percent change in body fat was -4.1 ± 3.8%. These results support H_1 which states there will be statistically significant reductions in weight, fat mass (FM) and percent body fat in the high protein group versus the normal carbohydrate group. Therefore, H_1 is accepted.

Table 11. *Body Composition*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Fat Free Mass (grams)	HP	42,201 ±5812	42,094 ±6,144	42,423 ±6,636	Group	.454	.95	.04	.21
	NCHO	40,227 ±4,745	40,354 ±4,880	40,804 ±5,293	Time	.164	1.9	.07	.37
	E	39,661 ±4,110	40,164 ±4,212	40,019 ±4,329	G x T	.325	1.2	.04	.36
	Time Mean	40,696 ±4,889	40,871 ±5,079	41,082 ±5,419					
Fat Mass (grams)	HP	32,776$^{\ddagger\Gamma\Sigma}$ ±6,037	29,979 ±5,699	29,425$^{\Omega}$ ±5,629	Group	.600	.51	.02	.13
	NCHO	32,442 ±6,974	30,990 ±6,864	30,578 ±6,816	Time	.000*	47.14	.65	1.00
	E	29,887 ±6,174	29,052$^{\Omega}$ ±5,962	29,066$^{\Omega}$ ±6,088	G x T	.000*	5.62	.18	.98
	Time Mean	31,662^{2,3} ±6,395	29,979^{1} ±6,175	29,667^{1} ±6,178					
Lean Mass (grams)	HP	40,411 ±5,560	40,330 ±5,882	40,635 ±6,406	Group	.454	.801	.03	.18
	NCHO	38,698 ±4,577	38,726 ±4,810	39,183 ±5,241	Time	.218	1.57	.06	.32
	E	38,130 ±4,062	38,637 ±4,150	38,483 ±4,266	G x T	.325	1.18	.04	.36
	Time Mean	39,080 ±4,733	39,231 ±4,951	39,434 ±5,304					
Body Fat (%)	HP	43.5$^{\Sigma}$ ±3.7	41.5$^{\eta}$ ±3.8	40.9$^{\eta\Omega}$ ±4	Group	.438	.839	.03	.19
	NCHO	44.2$^{\ddagger\Gamma\psi\Sigma}$ ±3.5	43.0 ±3.6	42.5 ±3.5	Time	.000*	39.94	.61	1.00
	E	42.7 ±3.7	41.7$^{\eta}$ ±3.7	41.8$^{\eta}$ ±3.5	G x T	.009*	3.57	.12	.86
	Time Mean	43.5^{3} ±3.6	42.1^{3} ±3.7	41.7^{1,2} ±3.7					
Bone Mineral Area (cm2)	HP	1,721 ±177	1,693 ±192	1,707 ±179	Group	.092	2.49	.09	.48
	NCHO	1,684 ±73	1,675 ±77	1,669 ±86	Time	.113	2.27	.08	.44
	E	1,613 ±109	1,608 ±108	1,628 ±102	G x T	.201	1.52	.06	.46
	Time Mean	1,673 ±120	1,659 ±126	1,668 ±367					

Table Continues

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Bone Mineral Content (grams)	HP	1,789 ±427	1,767 ±454	1,788 ±439	Group	.046*	3.28	.11	.60
	NCHO	1,622 ±213	1,628 ±213	1,621 ±228	Time	.324	1.15	.04	.24
Bone Mineral Density (g/cm2)	E	1,531 ±183	1,527 ±179	1,535 ±182	G x T	.258	1.35	.05	.41
	Time Mean	1,647 ±274	1,641 ±282	1,648 ±283					
	HP	1.0289 ± .15	1.0271 ± .15	1.0356 ± .16	Group	.093	2.49	.09	.48
	NCHO	.9606$^{\Omega\Psi\Sigma}$ ± .10	.9687$^{\Omega\Psi\Sigma}$ ± .11	.9660$^{\Omega\Psi\Sigma}$ ± .10	Time	.886	.121	.01	.07
	E	.9528$^{\Omega\Psi\Sigma}$ ± .09	.9500$^{\Omega\Psi\Sigma}$ ± .08	.9432$^{\Omega\Psi\Sigma}$ ± .08	G x T	.030*	3.28	.11	.82
	Time Mean	.9808 ±.11	.9819 ±.11	.9816 ±.11					

Note: Data represents body composition variables for the study. LSD post hoc analysis is indicated by the following superscripts: Ω= represents p< 0.05 difference from mean HP T1; Ψ= represents p< 0.05 difference from mean HP T2; ∑= represents p< 0.05 difference from mean HP T3; η= represents p< 0.05 difference from mean NCHO T1; ‡= represents p< 0.05 difference from mean E T2; Γ= represents p< 0.05 difference from mean E T3; LSD post hoc analysis for time main effects is indicated numerically (p< 0.05): 1= represents p< 0.05 difference from mean T1; 2= represents p< 0.05 difference from mean T2; 3= represents p< 0.05 difference from mean T3.

Bone mineral density was found to be statistically significant in group x time interaction (p=0.030). Results of the LSD post hoc analysis to follow up the group x time interaction for bone mineral density revealed that there were significant differences between all time points in the HP group as compared to all time points for the NCHO and E group. The percent changes for bone mineral density are as follows: HP 0.65 ±1.3%, NCHO 0.54 ± 2.0% and E only -0.92 ± 2.5%. There were no statistically significant

findings for group and time effects or group x time interaction for bone mineral area.

Bone mineral content was significant in group effects only (p=0.046).

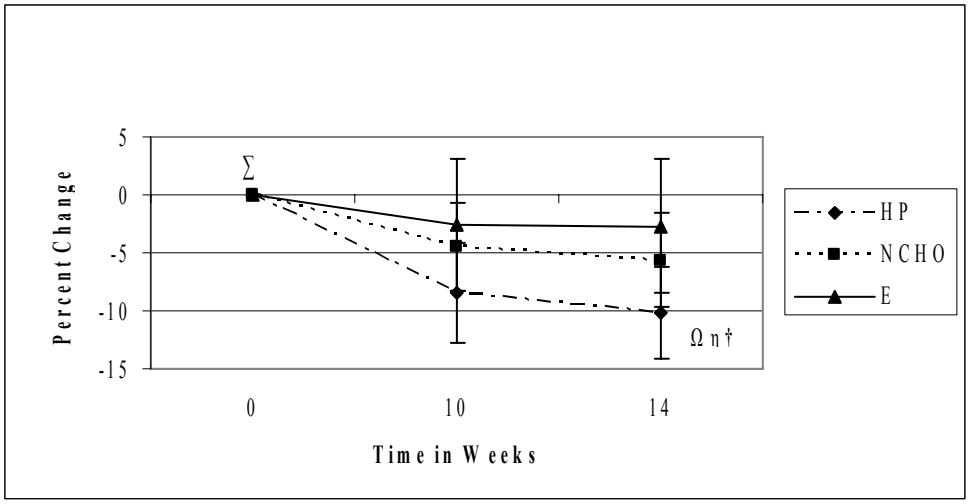

Figure 5. Data above represents percent change in fat mass across the three groups. Least Significant Differences (LSD) post hoc analysis indicates the group x time interaction (p=.001) shown above between all three groups at baseline indicated by the symbols Ω, η & † (HP T1, NCHO T1 and E T1 respectively) and HP group at T3 indicated by the symbol ∑.

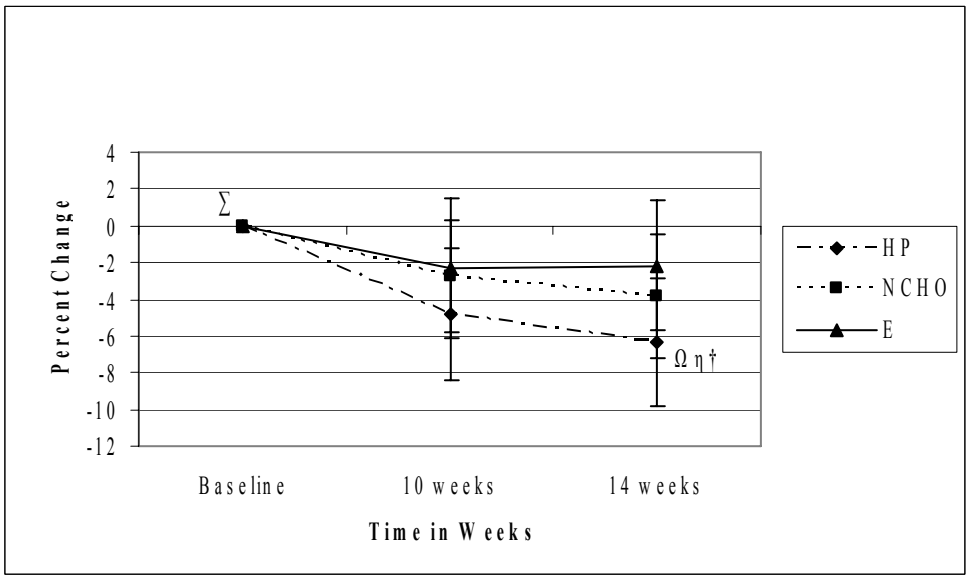

Figure 6. Data above represents percent change in body fat percentage across the three groups. Least Significant Differences (LSD) post hoc analysis indicates the group x time interaction (p=.001) shown above between all three groups at baseline indicated by the symbols Ω, η & † (HP T1, NCHO T1 and E T1 respectively) and HP group at T3 indicated by the symbol ∑.

Anthropometric Measurements

Hip and Waist Measurements. Table 12 summarizes changes in waist and hip measurements. There were significant group main effect ($p=0.022$) and time main effects ($p<0.001$) for changes in waist measures during the 14 week intervention. There was a significant time main effect ($p<0.001$) and a significant and group x time interaction ($p=0.012$) for hip circumference reduction. Results of LSD Post hoc analysis for hip circumference showed differences between HP time 1 and time 2 and NCHO time 1 and E time 3 ($p<0.05$). There were not statistically significant changes in waist to hip ratio as summarized below. There were significant differences in hip circumference, however not specifically for waist to hip ratio. The mean percent changes in waist circumference are as follows: HP -3.8 ± 3.7%, NCHO -1.7 ± 3.2%, E -.95 ± 2.1%. The overall mean percent change over time was -2.1 ± 3.3%. The significant mean percent changes in hip circumference are as follows: HP -3.4 ± 2.5%, NCHO -1.9 ± 2.9% and E -1.4 ± 2.2%. The overall mean percent change in hip circumference over time was -2.2 ± 2.6%. These findings do not support H_2 which states there will be statistically significant reductions in the waist to hip ratio in the high protein group as compared to the normal carbohydrate group. Therefore, H_2 is rejected.

Serum Hormone and Metabolic Variables

Hormone and Metabolic Markers. Table 13 summarizes findings of serum appetite regulating hormones and glucose values. There were stastically significant increases in fasting insulin levels that were significant by time main effect ($p<0.000$ and group x time interaction ($p=0.013$).

Table 12. *Anthropometric Measurements*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Waist (cm)	HP	91 ±8	89 ±8	88 ±8	Group	.022*	4	.14	.70
	NCHO	90 ±12	89 ±11	88 ±12	Time	.000*	13	.35	.99
	E	89 ±8	88 ±8	88 ±8	G x T	.095	2	.08	.59
	Time Mean	90^{3} ±9	89^{3} ±9	$88^{1,2}$ ±9					
Hip (cm)	HP	$113^{\ddagger\Gamma\beta\mu\sum}$ ±9	109 ±8	109^{Ω} ±8	Group	.385	.97	.04	.21
	NCHO	110 ±6	109^{Ω} ±7	108^{Ω} ±8	Time	.000*	20.56	.45	1.00
	E	108 ±8	107^{Ω} ±8	106^{Ω} ±7	G x T	.012*	3.37	.12	.83
	Time Mean	110 ±7	$108^{1,3}$ ±8	$108^{1,2}$ ±8					
Waist Hip Ratio	HP	.810 ±.06	.810 ±.05	.800 ±.05	Group	.697	.36	.02	.11
	NCHO	.810 ±.09	.820 ±.07	.810 ±.07	Time	.312	1.22	.05	.25
	E	.820 ±.05	.830 ±.06	.830 ±.06	G x T	.634	.64	.03	.20
	Time Mean	.813 ±.07	.820 ±.06	.813 ±.06					

Note: Circumference data are summarized above. LSD post hoc analysis is indicated by the following superscripts: Ω= represents p< 0.05 difference from mean HP T1 ∑= represents p< 0.05 difference from mean HP T3; β= represents p< 0.05 difference from mean NCHO T2; μ= represents p< 0.05 difference from mean NCHO T3; ‡= represents p< 0.05 difference from mean E T2; Γ= represents p< 0.05 difference from mean E T3. Post hoc follow up for time main effects are indicated numerically (p<0.05); 1= represents p< 0.05 difference from baseline mean; 2= represents p< 0.05 difference from mean T2; 3= represents p< 0.05 difference from mean T3.

Results of LSD Post hoc analysis for fasting insulin showed differences between HP time 1 as compared to NCHO time 2 and 3 (p< 0.05). The mean percent changes in insulin among groups were as follows: HP 112.3 ± 161.9%, NCHO 69.4 ± 71.9% and E 57.3 ± 62.6%. The overall mean percent change over time for insulin was

78.5 ± 105.6%. HOMA-IR was shown to be statistically significant for time main effect ($p<0.000$) but not in group x time interaction ($p=0.673$). The HOMA-IR mean percent changes across groups are as follows: HP 104.2 ± 158.9%, NCHO 73.2 ± 80.9% and E 55.7 ± 79.1%. The total percent mean change for HOMA-IR was 76.4 ± 108.4%. Leptin values were statistically significant over time main effect ($p<0.001$) as well as group x time interaction ($p=0.000$). Results of the LSD post hoc analysis to follow up the group x time interaction for leptin revealed that there were no significant individual mean differences. The mean percent changes between groups for leptin are as follows: HP -42.1 ± 21.3%, NCHO 43.4 ± 56.1% and E .80 ± 35.1%. The total mean percent change for leptin was 3.5 ± 53.7%. Ghrelin was noted to be statistically significant in time main effect ($p<0.000$) and group x time interaction ($p=0.006$). Results of the LSD post hoc analysis for ghrelin showed differences between HP T1 and HP T3, NCHO T2, T3 and E T1 and T2 ($p < 0.05$). The mean percent changes over the 14-week study between groups for ghrelin are as follows: HP -40.5 ± 28.7%, NCHO 24.9 ± 63.9% and E 0.86 ± 44.5%. The overall mean percent change over time for ghrelin was -3.5 ± 54.9%.

These findings are not supportive of H_3 which states there will be statistically significant reductions in glucose variables (e.g., fasting glucose and insulin) in the diet groups as compared to the exercise only groups, therefore H_3 is rejected. These findings are not supportive of H_4 which states there will be statistically significant improvement in hormonal levels among all three groups. Therefore, H_4 is rejected.

Table 13. *Serum Hormone and Metabolic Variables*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Glucose (mg/dL)	HP	97 ±6	97 ±7	94 ±10	Group	.432	.86	.04	.19
	NCHO	94 ±9	97 ±7	101 ±11	Time	.521	.66	.03	.16
	E	102 ±8	103 ±9	101 ±11	G x T	.067	2.28	.04	.19
	Time Mean	98 ±8	99 ±8	99 ±11					
Insulin (µU/mL)	HP	11 ±10	13 ±9	14 ±9	Group	.651	.43	.02	.12
	NCHO	10 ±7	8 ±4	15 ±8	Time	.000*	16.76	.44	.10
	E	11 ±8	14 ±9	16 ±10	G x T	.757	.28	.05	.09
	Time Mean	10 ±8	11[1,3] ±8	15[1,2] ±9					
Insulin Sensitivity (HOMA-IR)	HP	3 ±4	5 ±5	5 ±4	Group	.420	.89	.04	.19
	NCHO	3 ±2	2 ±1	4 ±2	Time	.000*	11.27	.36	.99
	E	3 ±3	4 ±3	4 ±3	G x T	.673	.400	.021	.110
	Time Mean	3 ±3	3[1,3] ±3	4[1,2] ±3					
Adipo-nectin (µg/mL)	HP	12 ±4	13 ±6	15 ±13	Group	.844	.17	.01	.08
	NCHO	13 ±6	13 ±5	19 ±16	Time	.033*	3.73	.16	.65
	E	13 ±8	14 ±9	19 ±17	G x T	.906	.25	.01	.10
	Time Mean	13[2,3] ±7	14[1] ±7	18[1] (±15					
Ghrelin (pg/ml)	HP	702[Σ] ±220	586 ±265	405[Ω‡ſ] ±221	Group	.378	.10	.05	.21
	NCHO	623 ±236	729[Σ] ±209	704[Σ] ±283	Time	.000*	10.71	.36	.98
	E	755[Σ] ±416	812[Σ] ±351	642 ±439	G x T	.006*	3.93	.17	.89
	Time Mean	701 ±291	706[1,3] ±275	597[1,2] ±314					

Table Continues

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Leptin (ng/ml)	HP	62 ±18	39 ±16	35 ±16	Group	.218	1.58	.07	.32
	NCHO	38 ±16	32 ±21	51 ±25	Time	.001*	8.46	.29	.95
	E	35 ±14	33 ±25	35 ±18	G x T	.000*	11.50	.35	1.00
	Time Mean	45^{2} ±16	$35^{1,3}$ ±21	40^{2} ±21					

Note: Data represents serum metabolic and hormonal levels for the study. LSD post hoc analysis is indicated by the following superscripts: *Note*: Data above represents body weight for the study. LSD post hoc analysis is indicated by the following superscripts: Ω= represents p< 0.05 difference from mean HP T1; ∑= represents p< 0.05 difference from mean HP T3; η= represents p< 0.05 difference from mean NCHO T1; β= represents p< 0.05 difference from mean NCHO T2; μ= represents p< 0.05 difference from mean NCHO T3; †= represents p< 0.05 difference from mean E T1; ‡= represents p< 0.05 difference from mean E T2; Γ= represents p< 0.05 difference from mean E T3; Post hoc follow up for time main effects are indicated numerically (p<0.05); 1= represents p< 0.05 difference from baseline mean; 2= represents p< 0.05 difference from mean T2; 3= represents p< 0.05 difference from mean T3.

Serum Chemistry: Lipid Panel. Table 14 summarizes trends noted in the lipid levels of each group. There was an upward trend in triglyceride levels noted in the NCHO and E groups without group effect (p=0.898), time effect (p<0.561) or group x time interaction (p=0.790). The HP group had a slight decrease in fasting triglycerides. The group percent changes in triglycerides were as follows: HP 4.7 ± 41.6%, NCHO 11.5 ± 30.5%, E 5.5 ± 24.3%. The overall mean percent change in triglyceride levels was 7.3 ± 32.2%. Table 14 supports alternate hypotheses H01 and H02 which state there will be no statistically significant differences in HDL values between groups and there will be no statistically significant differences in HDL values over time, respectively. The results reject H_5 which states there will be statistically significant reductions in lipid variables among diet groups as compared to the exercise only group.

Table 14. *Serum Chemistry: Lipid Panel*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Triglycerides (mg/dl)	HP	159 ±81	139 ±74	157 ±84	Group	.898	.107	.00	.07
	NCHO	158 ±74	167 ±87	167 ±75	Time	.561	.586	.02	.14
	E	142 ±95	171 ±125	147 ±95	G x T	.790	.237	.01	.09
	Time Mean	153 ±83	159 ±95	157 ±85					
Total Cholesterol (mg/dl)	HP	214 ±32	217 ±28	204 ±24	Group	.343	1.09	.04	.23
	NCHO	190 ±53	198 ±29	197 ±33	Time	.060	2.98	.11	.55
	E	200 ±36	207 ±41	196 ±37	G x T	.344	1.14	.04	.35
	Time Mean	201 ±40	207 ±33	199 ±31					
Low Density Lipoprotein (mg/dL)	HP	122 ±25	124 ±24	120 ±25	Group	.455	.799	.03	.18
	NCHO	109 ±38	107 ±22	107 ±25	Time	.227	1.53	.06	.31
	E	115 ±35	122 ±33	115 ±32	G x T	.658	.608	.02	.19
	Time Mean	115 ±33	118 ±23	114 ±27					
High Density Lipoprotein (mg/dL)	HP	58 ±19	57 ±16	56 ±13	Group	.876	.133	.01	.07
	NCHO	53 ±7	55 ±12	57 ±14	Time	.920	.083	.00	.06
	E	54 ±15	54 ±17	54 ±16	G x T	.430	.966	.04	.30
	Time Mean	55 ±14	55 ±15	56 ±14					

Note: Data represents serum lipid levels in the study.

Serum Chemistry: Clinical Safety Markers (Liver Function). Table 15 summarizes the trends noted in standard clinical chemistries. These labs were monitored primarily for participant safety. Significance was noted for time main effect ($p<0.003$) and group x time interaction ($p=0.001$) for Alanine Aminotransferase (ALT). There was

significance in time main effect ($p < 0.007$) and group x time interaction for total bilirubin ($p=0.028$). However, these changes were within the normal range for these values (Gomella, 1993). There were statistically significant changes in group, time or group x time for the following variables: Gamma Glutamyl Transpeptidase, Alkaline Phosphatase and Aminotransferase (AST). These findings support the null hypothesis H03 that states there will be no statistically significant changes in standard clinical chemistries assessing general health status. Therefore, H03 is accepted.

Table 15. *Serum Chemistry: Clinical Safety Markers (Liver Function)*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Gamma Glutamyl Trans-peptidase (U/L)	HP	34 ±7	35 ±13	31 ±9	Group	.266	1.36	.05	.28
	NCHO	49 ±39	48 ±43	44 ±30	Time	.132	2.11	.08	.41
	E	38 ±16	44 ±19	36 ±11	G x T	.395	1.03	.04	.32
	Time Mean	40 ±21	42 ±25	37 ±17					
Alkaline Phosph-atase (U/L)	HP	61 ±32	63 ±18	64 ±18	Group	.292	1.26	.05	.26
	NCHO	75 ±31	72 ±27	79 ±29	Time	.130	2.12	.08	.42
	E	68 ±24	76 ±27	74 ±27	G x T	.224	1.45	.06	.44
	Time Mean	68 ±29	70 ±24	72 ±25					
Alanine Amino-transferase (U/L)	HP	27 ±4	28 ±4	24^{μ} ±3	Group	.853	.160	.01	.07
	NCHO	26 ±4	27 ±5	28^{Σ} ±4	Time	.003*	6.66	.21	.90
	E	26 ±3	28 ±5	26 ±4	G x T	.001*	5.24	.17	.96

Table Continues

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
	Time Mean	262 ±4	281 ±5	262 ±4					
Aspartate Amino-transferase (U/L)	HP	21 ±4	23 ±11	22 ±8	Group	.162	1.89	.07	.38
	NCHO	21 ±7	18 ±5	18 ±4	Time	.832	.184	.01	.08
	E	21 ±6	20 ±6	21 ±6	G x T	.132	1.81	.07	.54
	Time Mean	21 ±6	20 ±8	20 ±6					
Total Bilirubin (mg/dL)	HP	$.44^{\Sigma\Gamma}$ ±.15	.39 ±.16	$.33^{\Omega}$ ±.13	Group	.241	1..46	.05	.30
	NCHO	.43 ±.15	.41 ±.15	.44 ±.19	Time	.007*	5.42	.18	.82
	E	.38 ±.09	.34 ±.10	$.33^{\Omega}$ ±.10	G x T	.028*	2.83	.10	75
	Time Mean	$.42^{3}$ ±.13	38 ±14	$.37^{1}$ ±14					

Note: Data represents serum metabolic/enzyme levels for the study. LSD post hoc analysis is indicated by the following superscripts: *Note*: Data above represents body weight for the study. LSD post hoc analysis is indicated by the following superscripts: Ω= represents p< 0.05 difference from mean HP T1; ∑= represents p< 0.05 difference from mean HP T3; μ= represents p< 0.05 difference from mean NCHO T3; Γ= represents p< 0.05 difference from mean E T3; Post hoc follow up for time main effects are indicated numerically (p<0.05); 1= represents p< 0.05 difference from baseline mean; 2= represents p< 0.05 difference from mean T2; 3= represents p< 0.05 difference from mean T3.

Metabolic Safety Markers. Table 16 summarizes the trends noted in metabolic safety markers. These levels were also monitored primarily for participant safety. There were no statistically significant findings for group main effect, time main effect, or group x time interaction for the following variables: total creatinine kinase, total protein, albumin, blood urea nitrogen, creatinine, BUN:creatinine ratio and calcium. The findings below also support the alternate hypothesis H03 that states there will be no statistically significant changes in standard clinical chemistries assessing general health status.

Table 16. *Metabolic Safety Markers*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Total Creatinine Kinase (IU/L)	HP	77 ±52	78 ±55	69 ±42	Group	.208	1.62	.06	.33
	NCHO	56 ±55	54 ±40	43 ±25	Time	.658	.421	.02	.12
	E	59 ±46	59 ±45	62 ±52	G x T	.858	.329	.01	.12
	Time Mean	64 ±55	64 ±47	58 ±40					
Total Protein (g/dl)	HP	7 ±.49	7 ±.32	7 ±.46	Group	.831	.19	.01	.08
	NCHO	7 ±.94	7 ±.43	7 ±.41	Time	.286	1.27	.02	.26
	E	7 ±.57	7 ±.61	7 ±.86	G x T	.217	1.48	.06	.43
	Time Mean	7 ±.67	7 ±.45	7 ±.58					
Albumin (g/dl)	HP	4 ±.34	4 ±.28	4 ±.26	Group	.732	.313	.01	.10
	NCHO	4 ±.58	4 ±.36	4 ±.35	Time	.395	.945	.04	.21
	E	4 ±.25	4 ±.30	4 ±.28	G x T	.176	1.62	.06	.48
	Time Mean	4 ±.39	4 ±.31	4 ±.29					
Blood Urea Nitrogen (BUN) (mg/dl)	HP	18 ±6	18 ±5	17 ±4	Group	.624	.475	.02	.12
	NCHO	16 ±4	17 ±4	17 ±5	Time	.650	.434	.02	.12
	E	16 ±5	17 ±4	16 ±4	G x T	.526	.803	.03	.25
	Time Mean	17 ±5	17 ±4	17 ±4					
Creatinine (mg/dl)	HP	.88 ±.16	.93 ±.15	.86 ±.18	Group	.943	.058	.00	.06
	NCHO	.87 ±.21	.88 ±.15	.93 ±.18	Time	.204	1.64	.06	.33
	E	.87 ±.16	.88 ±.12	.89 ±.14	G x T	.090	2.53	.09	.48
	Time Mean	.87 ±.18	.89 ±.14	.89 ±.17					

Table Continues

BUN: Creatinine Ratio	HP	20 ±4	19 ±5	20 ±6	Group	.554	.589	.02	.14
	NCHO	19 ±6	19 ±4	19 ±5	Time	.967	.033	.00	.06
	E	18 ±4	19 ±4	18 ±4	G x T	.768	.455	.02	.15
	Time Mean	19 ±5	19 ±4	19 ±5					
Calcium (mg/dl)	HP	9 ±.61	9 ±.34	9 ±.42	Group	.184	1.75	.06	.35
	NCHO	9 ±.93	9 ±.44	9 ±.42	Time	.210	1.61	.03	.24
	E	9 ±.33	9 ±.43	10 ±.38	G x T	.377	1.07	.04	.33
	Time Mean	9 ±.62	9 ±.40	9 ±.41					

Note: Data represents metabolic safety markers for the study.

Whole Blood Cell Analysis. Table 17 summarizes the whole blood analysis findings. These parameters were measured as a means of ensuring safety to all participants during the study intervention as well as monitoring for underlying disease (i.e., anemia, infection, etc.) that could affect test variables during the intervention. Basophil levels were noted to have statistically significant group main effect ($p=0.035$). Hemoglobin and levels were also noted to be statistically significant in time main effect ($p<0.048$). There was no group, time or group x time effects in the following variables: white blood cells, neutrophils, lymphocytes, monocytes, eosinophils, red blood cells or hematocrit. These findings are consistent with the accepted H03 that states, there will be no statistically significant changes in standard clinical chemistries assessing general health status.

Table 17. *Whole Blood Cell Values*

Variable	Group	T1	T2	T3	Source	Sig. (p-Value)	F	ηp^2	Power
White Blood Cells (K/µl)	HP	5.9 ±1.2	5.6 ±1.3	5.7 ±1.2	Group	.566	.576	.02	.14
	NCHO	5.6 ±1.7	5.3 ±1.3	6.3 ±1.9	Time	.264	1.37	.06	.28
	E	6.4 ±3.2	6.6 ±3.4	6.3 ±3.4	G x T	.073	2.35	.09	.60
	Time Mean	5.9 ±1.0	5.8 ±2.0	6.2 ±2.2					
Neutrophils (K/µl)	HP	3,271 ±960	3,102 ±1,055	3,075 ±912	Group	.917	.087	.00	.06
	NCHO	3,139 ±1484	3,139 ±890	3,608 ±1,684	Time	.815	.205	.01	.08
	E	3,253 ±1234	3,257 ±1,250	3,083 ±1,249	G x T	.232	1.43	.06	.43
	Time Mean	3,221 ±1226	3,166 ±1,065	3,255 ±1,282					
Lymphocytes (K/µl)	HP	1,839 ±597	1,716 ±522	1,907 ±519	Group	.774	.257	.01	.09
	NCHO	1,718 ±483	1,574 ±480	1,860 ±592	Time	.079	2.68	.10	.51
	E	1,716 ±612	1,765 ±498	1,710 ±641	G x T	.144	1.76	.07	.52
	Time Mean	1,758 ±564	1,685 ±500	1,826 ±584					
Monocytes (K/µl)	HP	493 ±148	474 ±147	467 ±123	Group	.707	.349	.01	.10
	NCHO	481 ±116	383 ±182	561 ±130	Time	.321	1.16	.05	.24
	E	497 ±144	517 ±159	512 ±180	G x T	.076	2.19	.09	.63
	Time Mean	490 ±136	458 ±163	513 ±144					
Basophils (K/µl)	HP	72 ±18	62 ±16	65 ±30	Group	.035*	3.59	.13	.64
	NCHO	65 ±27	53 ±18	58 ±26	Time	.158	1.92	.08	.38
	E	73 ±24	79 ±28	75 ±32	G x T	.192	1.56	.06	.47
	Time Mean	70 ±23	65 ±21	66 ±29					
Eosinophils (K/µl)	HP	189 ±82	177 ±69	172 ±63	Group	.120	2.22	.09	.43
	NCHO	164 ±68	166 ±79	181 ±61	Time	.654	.428	.02	.12
	E	214 ±87	211 ±93	224 ±88	G x T	.658	.608	.03	.19

Table Continues

Variable	Group	T1	T2	T3	Source	Sig. (p-Value)	F	ηp^2	Power
	Time Mean	189 ±79	185 ±80	192 ±71					
Red Blood Cells (M/µl)	HP	4.6 ±.47	4.5 ±.51	4.4 ±.32	Group	.646	.441	.02	.12
	NCHO	4.6 ±.40	4.6 ±.47	4.5 ±.42	Time	.145	2.01	.08	.40
	E	4.5 ±.37	4.5 ±.37	4.5 ±.35	G x T	.622	.660	.03	.21
	Time Mean	4.6 ±.41	4.5 ±.45	4.5 ±.36					
Hemoglobin (g/dl)	HP	13.3 ±1.3	13.2 ±.96	12.7 ±.78	Group	.565	.578	.02	.14
	NCHO	13.5 ±1.1	13.3 ±1.2	13.2 ±1.2	Time	.048*	3.25	.12	.59
	E	13.2 ±1.2	12.9 ±.98	12.9 ±1.1	G x T	.537	.787	.03	.24
	Time Mean	13.3[3] ±1.2	13.1 ±1.0	12.9[1] ±1.0					
Hematocrit (%)	HP	42 ±4	42 ±3	41 ±3	Group	.517	.669	.03	.16
	NCHO	43 ±3	43 ±4	42 ±4	Time	.370	1.01	.04	.22
	E	42 ±4	42 ±3	42 ±3	G x T	.813	.393	.02	.14
	Time Mean	42 ±4	42 ±3	42 ±3					

Note: Data represents differential white blood cell levels for the study.

βeta-Hydroxybutyrate. Table 18 summarizes ketone values for each group in the study. The ketone levels were monitored to show that the prescribed dietary intervention, specifically the High Protein diet did not produce excessive serum levels of ketone and were safe during the course of this study intervention. There were no statistically significant changes noted in ketone levels in group main effect ($p=0.570$), time main effect ($p<0.411$) and group x time interaction ($p=0.077$). Trends were noted to decrease in the HP and NCHO groups while the E group went up slightly.

Table 18. *Beta-Hydroxybutyrate*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Beta-Hydroxy-butyrate	HP	.087 ±.05	.082 ±.05	.057 ±.04	Group	.570	.569	.03	.14
	NCHO	.078 ±.05	.051 ±.03	.054 ±.05	Time	.411	.908	.04	.20
	E	.059 ±.04	.079 ±.09	.079 ±.07	G x T	.077	2.19	.09	.62
	Time Mean	.075 ±.05	.071 ±.06	.063 ±.05					

Note: Data represents ketone levels for the study.

Cardiovascular Parameters

Resting Heart Rate & Blood Pressure. Table 19 summarizes cardiovascular data below that reflect significant changes in resting heart rate ($p<0.050$), systolic ($p<0.009$) and diastolic blood pressure for time main effects ($p<0.002$). There were no significant group x time interaction for resting heart rate ($p=0.472$), systolic blood pressure ($p= 0.921$) and diastolic blood pressure ($p=0.534$). There were no significant effects in group main effects for resting heart rate, ($p=0.637$), systolic blood pressure ($p=0.984$) or diastolic blood pressure ($p=0.534$).

The mean group percent changes for resting heart rate are as follows: HP -5.8 ± 21.5%, NCHO -2.3 ± 14.7%, E -7.1 ± 14.9%. The overall percent reduction in resting heart rate was -4.9 ± 16.9%. The mean group percent changes for systolic blood pressure over time are as follows: HP -2.4 ± 14.2%, NCHO 0.54 ± 12.9% and E -2.1 ± 13.2%. The overall percent change reduction in systolic blood pressure was -1.2 ± 13.2%. The mean percent changes for diastolic blood pressure for each group are as follows: HP -4.0 ± 16.2%, NCHO -1.5 ± 12.9% and E -5.8 ± 16.6%. The overall mean percent change reduction over time in diastolic blood pressure was -3.7 ± 15.1%.

These results fulfill H_6 which states that there will be statistically significant reductions in resting cardiovascular parameters in all three groups due to time effects noted above. Therefore, H6 is accepted.

Table 19. *Resting Heart Rate and Blood Pressure*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Resting Heart Rate (bpm)	HP	74 ±11	70 ±7	71 ±12	Group	.637	.46	.02	.12
	NCHO	76 ±14	72 ±12	75 ±13	Time	.050*	3.22	.06	.57
	E	77 ±14	74 ±10	72 ±9	G x T	.472	.89	.03	.28
	Time Mean	76[3] ±13	72 ±10	73[1] ±11					
Resting Systolic Blood Pressure (mmHg)	HP	126 ±16	120 ±13	122 ±11	Group	.984	.02	.00	.05
	NCHO	125 ±12	119 ±9	124 ±14	Time	.009*	5.20	.17	.81
	E	126 ±10	118 ±12	123 ±13	G x T	.921	.23	.01	.09
	Time Mean	126[2] ±13	119[1,3] ±11	123[2] ±13					
Resting Diastolic Blood Pressure (mmHg)	HP	75 ±10	72 ±9	71 ±7	Group	.651	.43	.02	.12
	NCHO	74 ±10	69 ±8	72 ±9	Time	.002*	6.86	.21	.91
	E	78 ±10	71 ±9	72 ±8	G x T	.534	.79	.03	.25
	Time Mean	76 ±10	71[1,3] ±9	72[1,2] ±8					

Note: Data represents heart rate and blood pressure variables for the study. LSD post hoc analysis for time main effects is indicated numerically ($p< 0.05$). 1= represents $p< 0.05$ difference from baseline mean; 2= represents $p< 0.05$ difference from mean T2; 3= represents $p< 0.05$ difference from mean T3.

Resting Metabolic Variables

Resting Energy Expenditure. Table 20 illustrates that there are no statistically significant differences in group, time, group x time for resting energy expenditure

variables. This is consistent with H04 that states there will be no statistically significant time effect for resting energy expenditure in all three groups. Therefore, H04 is accepted.

Table 20. *Resting Metabolic Markers*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Resting Energy Expenditure (Kcal/min)	HP	.95 ±.10	.92 ±.13	.90 ±.14	Group	.816	.20	.01	.08
	NCHO	.95 ±.15	.92 ±.14	.95 ±.13	Time	.146	1.99	.07	.39
	E	.92 ±.13	.90 ±.13	.93 ±.12	G x T	.317	1.19	.05	.36
	Time Mean	.94 ±.13	.91 ±.13	.93 ±.13					
Resting Energy Expenditure (Kcal/d)	HP	1,372 ±149	1,325 ±168	1,302 ±188	Group	.983	.02	.00	.05
	NCHO	1,358 ±211	1,313 ±198	1,356 ±181	Time	.060	2.97	.10	.55
	E	1,341 ±198	1,317 ±184	1,345 ±168	G x T	.324	1.18	.04	.36
	Time Mean	1,357 ±186	1,318 ±183	1,334 ±179					
Resting Energy Expenditure (Kcal/kg/d)	HP	16.94 ±1.80	17.18 ±1.72	16.89 ±2.55	Group	.455	.800	.030	.179
	NCHO	17.19 ±1.92	17.07 ±1.45	17.71 ±1.55	Time	.472	.761	.029	.172
	E	17.68 ±2.26	17.60 ±2.42	17.95 ±1.71	G x T	.546	.772	.029	.240
	Time Mean	17.27 ±1.99	17.28 ±1.86	17.52 ±1.94					

Note: Data represents resting metabolic markers for the study.

Stress Test Cardiovascular Parameters

Maximal Stress Test. Table 21 summarizes the results from the maximal stress test over the course of the 14 week study. There were significant time effects for peak VO_2 (mL/kg/min) ($p<0.000$) and maximal systolic blood pressure ($p<0.002$). There was no significant group x time interaction for peak VO_2 (mL/kg/min) ($p=0.273$). The group percent changes in peak VO_2 were as follows: HP: 17.3 ± 35.5%, NCHO 11.1 ± 17.5%, E 4.4 ± 16.1%. The overall percent change for peak VO_2 was 10.7 ± 23.7%. The maximal systolic blood pressure mean percent changes for individuals groups were as follows: HP -2.4 ± 14.8%, NCHO -4.7 ±15.3%, and E -11.6 ± 12.9%. The overall mean percent change for maximal systolic blood pressure was -6.4 ± 14.6%. No statistically significant differences were seen in peak heart rate and maximal diastolic blood pressure.

Table 21. *Stress Test Cardiovascular Parameters*

Variable	Group	T1	T3	Source	Sig. (p-Value)	F	ηp^2	Power
Peak VO_2 (mL/kg/min)	HP	17.1 ±3.7	19.3 ±3.1	Group	.110	2.31	.09	.45
	NCHO	15.7 ±2.2	17.3 ±2.8	Time	.000*	15.7 5	.24	.97
	E	17.7 ±3.4	18.3 ±3.5	G x T	.273	1.33	.05	.28
	Time Mean	16.8[2] ±3.1	18.3[1] ±3.1					
Peak Heart Rate (bpm)	HP	150 ±19	150 ±17	Group	.141	2.04	.07	.40
	NCHO	141 ±18	138 ±21	Time	.615	.26	.01	.08
	E	145 ±21	145 ±14	G x T	.825	.19	.01	.08
	Time Mean	145 ±19	144 ±17					

Table Continues

Variable	Group	T1	T3	Source	Sig. (p-Value)	F	ηp^2	Power
Peak Systolic BP (mmHg)	HP	157 ±24	156 ±20	Group	.791	.24	.01	.09
	NCHO	160 ±21	150 ±27	Time	.002*	10.72	.18	.89
	E	163 ±26	145 ±22	G x T	.300	1.23	.05	.26
	Time Mean	162[2] ±24	150[1] ±23					
Peak Diastolic BP (mmHg)	HP	73 ±12	73 ±12	Group	.869	.12	.00	.07
	NCHO	71 ±8	73 ±10	Time	.646	.21	.00	.07
	E	74 ±14	70 ±12	G x T	.554	.59	.02	.14
	Time Mean	73 ±11	72 ±11					

Note: Data represents maximal VO_2 testing variables for the study. LSD post hoc analysis for time main effects is indicated numerically ($p< 0.05$). 1= represents $p< 0.05$ difference from baseline mean; 2= represents $p< 0.05$ difference from mean T2.

The Six Minute Walk Test

Functional Cardiopulmonary Fitness Testing. In Table 22, the analysis of the Six Minute Walk Test is summarized. Statistical significance was noted for the time main effect ($p<0.000$) and group x time interaction ($p=0.000$). Post hoc analysis showed NCHO time 1 and E time 1 share a common mean that was significantly different than the common mean shared by HP Time 2, HP time 3 and NCHO time 3 ($p< 0.05$). The mean percent changes over time are as follows: HP 6.3 ± 10.2%, NCHO 7.3 ± 4.1% and E only 8.7 ± 11.7%. The overall mean percent change over time for the six minute walk test was 7.4 ± 8.9%.

Table 22. *Six Minute Walk Test*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
6MWT (Meters)	HP	533 ±72	$558^{\beta\Gamma}$ ±69	$564^{\beta\Gamma}$ ±79	Group	.218	1.58	.07	.32
	NCHO	511 ±48	$533^{\Psi\Sigma}$ ±43	546 ±41	Time	.000*	7.69	.15	1.00
	E	496 ±67	526 ±60	$535^{\Psi\Sigma}$ ±59	G x T	.000*	11.05	.34	.15
	Time Mean	$513^{2,3}$ ±62	$538^{1,3}$ ±57	$548^{1,2}$ ±60					

Note: Data represents 6MWT values for the study. LSD post hoc analysis is indicated by the following superscripts: Ψ= represents p< 0.05 difference from mean HP T2; ∑= represents p< 0.05 difference from mean HP T3; Post hoc follow up for time main effects are indicated numerically (p<0.05). 1= represents p< 0.05 difference from baseline mean 2= represents p< 0.05 difference from mean T2; 3= represents p< 0.05 difference from mean T3.

Strength Parameters

Upper and Lower Body Strength. Table 23 delineates changes in upper and lower body strength over the 14 week training intervention. There were significance changes in time main effect for one repetition maximal effort in the bench press (p<0.000) and leg press (p<0.000). There were significant time effects for bench press work volume (p=0.027) without group x time interaction (0.695). There were no statistically significant improvements in group, time or group x time effects for leg press work volume. The mean percent changes in bench press one repetition maximal effort among groups were as follows: HP 26.9 ± 37.5%, NCHO 14.8 ± 20.5%, E 23.1 ± 22.5%. The overall mean percent change over time one repetition maximum bench press was 21.3 ± 27.7%. The mean percent changes for one repetition maximal effort leg press are as follows: HP 37.7 ± 47.4%, NCHO 37.1 ± 38.8% and E 24.9 ± 23.6%. The overall mean percent change for one repetition leg press over time was 33.1 ± 36.9%. Based on the findings above, H_7 which states there will be statistically significant increases in body strength among all three groups is accepted.

Table 23. *Upper and Lower Body Strength Variables*

Variable	Group	T1	T3	Source	Sig. (p-value)	F	ηp^2	Power
Bench Press 1 Repetition Maximum (Kg)	HP	20.1 ±6.1	23.9 ±4.7	Group	.457	.80	.03	.18
	NCHO	20.7 ±5.4	22.9 ±5.8	Time	.000*	43.40	.46	1.00
	E	21.5 ±4.9	25.9 ±3.5	G x T	.412	1.71	.04	.20
	Time Mean	20.8[2] ±5.5	24.2[1] ±4.7					
Bench Press Work Volume (kg x repetitions)	HP	154.0 ±63.4	171.1 ±77.9	Group	.466	.774	.031	.174
	NCHO	124.5 ±68.5	165.0 ±72.5	Time	.027*	3.79	.07	.48
	E	155.4 ±84.2	178.9 ±56.4	G x T	.695	.45	.01	.07
	Time Mean	144.6[2] ±66.0	171.7[1] ±63.7					
Leg Press 1 Repetition Maximum (Kg)	HP	75.4 ±31.2	106.4 ±28.5	Group	.936	.07	.00	.06
	NCHO	82.2 ±32.0	105.7 ±36.4	Time	.000*	59.74	.55	1.00
	E	85.5 ±32.9	106.9 ±33.5	G x T	.639	.45	.02	.12
	Time Mean	82.5[2] ±32.0	106.3[1] ±32.8					
Leg Press Work Volume (kg x repetitions)	HP	1,462.9 ±923.7	1,348.6 ±469.6	Group	.144	1.88	.10	.46
	NCHO	1,042.2 ±539.1	1,411.8 ±864.3	Time	.128	2.39	.05	.33
	E	1,206.8 ±780.5	1,475.9 ±1,195	G x T	.200	1.66	.07	.33
	Time Mean	1,237.3 ±747.8	1,412.1 ±842.9					

Note: Data represents upper and lower body strength testing variables for the study. LSD post hoc analysis for time main effects is indicated numerically ($p < 0.05$). 1= represents $p < 0.05$ difference from baseline mean; 2= represents $p < 0.05$ difference from mean T2.

Neurocom SmartEquitest Results

Sensory Organization Test. Table 24 summarized finings in the Sensory Organization Test (SOT) for the composite equilibrium score, the weighted average of the scores of all sensory conditions, characterizes the overall level of performance. The composite equilibrium score which was significant for time main effect ($p<0.004$), however there were not significant group main effect ($p=0.645$) and group x time interaction ($p=0.969$).

Table 24. *Sensory Organization Test Variables*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
	HP	74.5	75.4	76.1	Group	.655	.44	.02	.12
Composite		±5.1	±3.3	±4.1					
Score	NCHO	75.6	76.5	77.9	Time	.004*	6.13	.20	.87
		±5.1	±6.4	±4.8					
	E	75.2	76.2	77.7	G x T	.969	.14	.01	.08
		±5.5	±4.9	±5.9					
	Time Mean	75.2[3]	76.0[3]	77.2[1,2]					
		±5.2	±4.9	±4.9					

Note: Data represents Sensory Organization variables for the study. LSD post hoc analysis for time main effects is indicated numerically ($p< 0.05$). 1= represents $p< 0.05$ difference from baseline mean; 2= represents $p< 0.05$ difference from mean T2; 3= represents $p< 0.05$ difference from mean T3.

Limits of Stability. Table 25 summarizes the results from the Limits of Stability (LOS) testing. There were no significant changes in the Limits of Stability testing in group main effect, time main effect or group x time interaction for the following variables: Limits of Stability Reaction Time, Movement Velocity, Endpoint Excursion, Maximum Excursion and Directional Control.

Table 25. *Limits of Stability Variables*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Limits of Stability Reaction Time (seconds)	HP	.95 ±.16	.92 ±.24	.93 ±.18	Group	.793	.23	.01	.09
	NCHO	.93 ±.26	.90 ±.36	.87 ±.29	Time	.932	.07	.00	.06
	E	.88 ±.18	.89 ±.22	.94 ±.19	G x T	.580	.72	.03	.23
	Time Mean	.92 ±.20	.90 ±.27	.91 ±.22					
Movement Velocity (degrees per second)	HP	3.5 ±.96	3.5 ±.95	3.6 ±1.3	Group	.413	.90	.03	.20
	NCHO	3.8 ±1.4	4.3 ±1.6	3.7 ±1.1	Time	.650	.43	.02	.12
	E	3.9 ±.77	3.5 ±1.2	3.5 ±1.2	G x T	.337	1.15	.04	.35
	Time Mean	3.7 ±1.0	3.8 ±1.3	3.6 ±1.2					
Endpoint Excursion (% of max LOS distance)	HP	73.2 ±12.5	73.4 ±12.5	77.0 ±11.9	Group	.412	.90	.03	.20
	NCHO	76.0 ±14.9	69.0 ±11.7	70.1 ±12.1	Time	.339	1.10	.04	.23
	E	71.7 ±15.9	68.3 ±16.9	69.7 ±13.8	G x T	.457	.92	.04	.28
	Time Mean	73.6 ±14.4	70.2 ±13.7	72.3 ±12.6					
Maximum Excursion (max distance)	HP	89.9 ±14.9	90.9 ±12.8	90.9 ±9.9	Group	.454	.80	.03	.18
	NCHO	90.8 ±12.1	86.4 ±10.9	86.3 ±9.9	Time	.357	1.05	.04	.22
	E	89.3 ±11.1	86.2 ±14.9	85.4 ±11.6	G x T	.717	.53	.02	.17
	Time Mean	90.0 ±12.7	87.8 ±12.9	87.5 ±10.5					
Directional Control (intended vs. extraneous movement)	HP	71.4 ±12.3	73.7 ±6.4	76.2 ±8.1	Group	.812	.21	.01	.08
	NCHO	73.2 ±10.3	71.2 ±10.4	73.0 ±7.2	Time	.551	.60	.02	.15
	E	73.3 ±10.6	74.3 ±8.1	73.7 ±9.5	G x T	.592	.70	.03	.22
	Time Mean	72.6 ±11.1	73.1 ±8.3	74.3 ±8.3					

Note: Data represents Limits of Stability variables for the study.

Step Up and Over Variables. Table 26 summarized results from the Step up and Over Variables (SUO). There were significant time main effects in the following areas: Step up and over, left up index, left leg (SUOLUIL) ($p<0.009$), Step up and over movement time, left leg (SUOMTLM) ($p<0.021$) and step up and over movement time, right leg (SUOMTRM) ($p<0.042$). There were no significant changes in the following step up and over variables for group main effect, time main effect or group x time interaction for the following: right leg lift up index, lift impact index for left and right leg,

Table 26. *Step Up and Over Variables*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Lift Up Index Left Leg (% of body weight)	HP	32.7 ±7.8	32.8 ±8.6	34.7 ±8.7	Group	.381	.98	.04	.21
	NCHO	34.1 ±7.6	37.1 ±7.3	37.4 ±7.5	Time	.009*	5.14	.17	.80
	E	36.0 ±6.5	35.6 ±7.5	37.5 ±7.2	G x T	.308	1.22	.05	.37
	Time Mean	34.3[3] ±7.3	35.2[3] ±7.8	36.5[1,2] ±7.8					
Lift Up Index Right Leg (% of body weight)	HP	37.7 ±8.5	38.0 ±8.3	37.8 ±8.5	Group	.834	.18	.01	.08
	NCHO	38.2 ±6.4	38.2 ±9.4	39.8 ±5.9	Time	.815	.21	.01	.08
	E	39.3 ±7.8	39.1 ±7.2	39.2 ±9.2	G x T	.929	.22	.01	.10
	Time Mean	38.4 ±7.6	38.4 ±8.3	38.9 ±7.9					

Table Continues

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Movement Time Left Leg (seconds)	HP	1.7 ±.33	1.6 ±.36	1.6 ±.35	Group	.780	.25	.01	.09
	NCHO	1.6 ±.27	1.6 ±.34	1.6 ±.34	Time	.021*	4.16	.14	.71
	E	1.8 ±.32	1.7 ±.25	1.5 ±.12	G x T	.356	1.11	.04	.34
	Time Mean	1.7 ±.31	1.6[1,3] ±.32	1.6[1,2] ±.27					
Movement Time Right Leg (seconds)	HP	1.6 ±.26	1.6 ±.31	1.6 ±.34	Group	.968	.03	.00	.06
	NCHO	1.7 ±.32	1.6 ±.25	1.6 ±.29	Time	.042*	3.38	.12	.61
	E	1.6 ±.25	1.6 ±.25	1.6 ±.22	G x T	.912	.25	.01	.10
	Time Mean	1.6 ±.28	1.6[1,3] ±.27	1.6[1,2] ±.28					
Left Lift Impact Index (% of body weight)	HP	52.1 ±20.4	51.2 ±18.2	51.0 ±17.7	Group	.530	.64	.03	.15
	NCHO	54.1 ±16.3	59.6 ±13.5	52.3 ±10.8	Time	.231	1.51	.06	.31
	E	49.4 ±19.9	49.4 ±18.4	49.4 ±17.8	G x T	.196	1.54	.06	.46
	Time Mean	51.9 ±18.9	53.4 ±16.7	50.9 ±15.4					
Right Lift Impact Index (% of body weight)	HP	52.5 ±21.2	53.2 ±16.7	53.4 ±15.4	Group	.211	1.60	.06	.32
	NCHO	51.5 ±13.3	55.1 ±14.9	52.5 ±16.8	Time	.570	.57	.02	.14
	E	45.4 ±17.3	45.8 ±17.7	43.8 ±18.8	G x T	.868	.31	.01	.12
	Time Mean	49.8 ±17.3	51.4 ±16.4	49.9 ±17.0					

Note: Data represents Step Up and Over variables for the study. LSD post hoc analysis for time main effects is indicated numerically ($p < 0.05$). 1= represents $p < 0.05$ difference from baseline mean; 2= represents $p < 0.05$ difference from mean T2; 3= represents $p < 0.05$ difference from mean T3.

Sit To Stand Variables

Sit To Stand Variables. Table 27 summarizes results for the Sit to Stand Test. The sit to stand rising index (STSRIM) showed improvement over time main effect ($p<0.003$) without group main effect or group x time interaction. The sit to stand left/right weight symmetry (STSACXM) variable showed positive gains over time main effect ($p<0.042$) without stastically significant gains in group main effect ($p=0.733$) or group x time interaction ($p=0.416$). There were no significant changes in the sit to stand testing in group main effect, time main effect or group x time interaction for the following variables: weight transfer and cog sway velocity. The lack of improvement with this modality does not support H_8 which states there will be statistically significant improvements in functional capacity in both diet groups on the four tests of balance. Therefore we reject H_8. The lack of improvement with all of the balance modalities supports the H05, which states there will be no statistically significant differences in between group effects on the four tests of balance.

Table 27. *Sit to Stand Variables*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Weight Transfer (sec.s)	HP	.37 ±.11	.37 ±.15	.39 ±.17	Group	.118	2.23	.08	.43
	NCHO	.37 ±.21	.35 ±.13	.35 ±.12	Time	.756	.281	.01	.09
	E	.41 ±.20	.48 ±.21	.46 ±.20	G x T	.670	.591	.02	.19
	Time Mean	.38 ±.23	.40 ±.25	.40 ±.24					

Table Continues

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Rising Index (% body Weight)	HP	13.8 ±2.9	15.5 ±3.6	14.9 ±3.6	Group	.972	.028	.00	.05
	NCHO	14.1 ±3.1	15.3 ±3.6	15.4 ±3.5	Time	.003*	6.54	.21	.89
	E	14.2 ±3.9	15.6 ±4.6	15.2 ±3.8	G x T	.973	.127	.01	.08
	Time Mean	14.0 ±3.3	15.5[1,3] ±3.9	15.2[1,2] ±3.6					
Center of Gravity Sway Velocity (degrees per second)	HP	4.3 ±.90	4.2 ±.99	3.9 ±.98	Group	.337	1.11	.04	.24
	NCHO	4.4 ±1.4	4.5 ±1.0	4.5 ±.82	Time	.190	1.72	.06	.34
	E	4.3 ±1.3	3.8 ±1.1	3.8 ±1.1	G x T	.186	1.58	.06	.47
	Time Mean	4.3 ±1.2	4.2 ±1.0	4.1 ±.97					
Left/Right Weight Symmetry (%)	HP	-2.6 ±9.2	-.12 ±10.9	-2.5 ±8.5	Group	.733	.312	.01	.10
	NCHO	-4.5 ±12.7	5.2 ±13.3	-.50 ±13.3	Time	.042*	3.39	.12	.61
	E	-.11 ±12.4	1.3 ±9.3	.11 ±8.9	G x T	.416	.992	.04	.30
	Time Mean	-2.4 ±11	2.1[1,3] ±11.2	-0.95[1,2] ±10.2					

Note: Data represents Sit to Stand variables for the study. LSD post hoc analysis for time main effects is indicated numerically ($p < 0.05$). 1= represents $p < 0.05$ difference from baseline mean; 2= represents $p < 0.05$ difference from mean T2; 3= represents $p < 0.05$ difference from mean T3.

Psychometric Questionnaires

Eating Satisfaction Questionnaire. Table 28 summarizes the findings of the Eating Satisfaction questionnaire. This questionnaire was included to maintain consistently in the previous Curves research interventions. Significance was noted in time main effects in the areas of feelings of fullness ($p<0.010$) and by group in quality of life ($p<0.047$). However, no significant changes were noted in time or group x time interactions for feelings of fullness ($p=0.771$) and quality of life ($p=0.406$) for these

variables. There were no statistically significant differences among the following variables: appetite, hunger, satisfaction of fullness and energy.

Table 28. *Eating Satisfaction*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Appetite	HP	5.9 ±1.2	5.4 ±1.4	5.6 ±.84	Group	.317	1.18	.05	.25
	NCHO	6.2 ±1.6	5.8 ±1.1	5.9 ±1.5	Time	.065	2.90	.11	.54
	E	6.5 ±1.2	6.3 ±1.4	5.8 ±1.4	G x T	.613	.672	.03	.21
	Time Mean	6.2 ±1.3	5.8 ±1.3	5.8 ±1.2					
Hunger	HP	5.3 ±1.5	4.7 ±2.1	4.8 ±1.5	Group	.820	.199	.01	.08
	NCHO	4.8 ±1.9	4.6 ±2.3	4.6 ±1.9	Time	.542	.620	.03	.15
	E	5.0 ±1.8	4.9 ±1.9	4.9 ±1.4	G x T	.985	.091	.00	.07
	Time Mean	5.0 ±1.7	4.7 ±2.1	4.8 ±1.6					
Satisfaction of Fullness	HP	6.9 ±1.2	6.3 ±1.7	6.7 ±1.2	Group	.383	.979	.04	.21
	NCHO	6.7 ±1.7	6.3 ±1.5	6.9 ±1.8	Time	.137	2.08	.08	.41
	E	6.4 ±1.4	6.0 ±1.4	6.2 ±1.3	G x T	.827	.374	.02	.13
	Time Mean	6.7 ±1.4	6.2 ±1.5	6.6 ±1.4					
Feelings of fullness	HP	6.2 ±1.4	6.3 ±1.8	6.9 ±1.3	Group	.207	1.63	.06	.33
	NCHO	5.9 ±1.4	5.8 ±1.1	6.6 ±1.5	Time	.010*	5.12	.18	.80
	E	6.0 ±1.3	5.4 ±2.1	6.1 ±1.5	G x T	.771	.452	.02	.15
	Time Mean	6.0 ±1.4	5.8[1,3] ±1.7	6.5[1,2] ±1.4					

TableContinues

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Energy	HP	5.8 ±1.8	6.6 ±1.6	6.9 ±1.4	Group	.252	1.42	.06	.29
	NCHO	5.3 ±1.8	5.8 ±1.6	6.2 ±1.5	Time	.058	3.02	.11	.56
	E	5.9 ±1.7	5.8 ±1.2	5.8 ±1.3	G x T	.405	1..01	.04	.31
	Time Mean	5.7 ±1.8	6.1 ±1.5	6.3 ±1.4					
Quality	HP	6.0 ±1.2	6.1 ±1.6	6.4 ±1.2	Group	.047*	3.27	.12	.60
	NCHO	5.7 ±1.5	5.8 ±1.4	6.7 ±1.4	Time	.082	.101	2.64	.50
	E	5.4 ±1.3	5.2 ±1.9	5.3 ±1.5	G x T	.406	.041	1.01	.31
	Time Mean	5.7 ±1.3	5.7 ±1.6	6.1 ±1.4					

Note: Data represents Eating Satisfaction variables for the study. LSD post hoc analysis for time main effects is indicated numerically ($p< 0.05$). 1= represents $p< 0.05$ difference from baseline mean; 2= represents $p< 0.05$ difference from mean T2; 3= represents $p< 0.05$ difference from mean T3.

Quality of Life- SF36. Table 29 summarizes findings from the Quality of Life-SF36 questionnaire. Time main effects were seen in general health ($p<0.020$), vitality ($p<0.031$) and mental health ($p=0.000$) but no significant interactions were observed among groups. These findings do not support hypothesis H_9, which states there will be statistically significant improvement in psychological status as measured via questionnaires among all three groups. Specifically, it is predicted that participants in all groups will demonstrate increased physical function and vitality and decreased physical pain, increased vigor scores and decreased depression. Therefore, H_9 is rejected.

Table 29. *Quality of Life- SF36*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Physical Functioning	HP	70.6 ±17.3	64.6 ±33.9	70.6 ±34.3	Group	.551	.604	.02	.15
	NCHO	73.4 ±14.3	75.0 ±18.1	73.9 ±16.1	Time	.082	2.64	.09	.50
	E	65.8 ±31.2	65.5 ±32.2	75.5 ±20.1	G x T	.271	1.31	.05	.40
	Time Mean	69.9 ±20.9	68.4 ±28.1	73.3 ±23.5					
Role Limitations	HP	78.3 ±37.3	83.1 ±20.7	83.1 ±16.0	Group	.781	.248	.01	.09
	NCHO	78.1 ±26.1	76.8 ±23.6	81.1 ±17.7	Time	.469	.769	.03	.17
	E	72.9 ±35.6	80.9 ±16.1	81.3 ±11.3	G x T	.860	.326	.01	.12
	Time Mean	72.5 ±33.0	80.3 ±20.1	81.8 ±15.0					
Bodily Pain	HP	74.7 ±18.3	75.1 ±18.6	74.7 ±14.4	Group	.353	1.07	.04	. 23
	NCHO	68.2 ±22.1	66.4 ±22.4	68.1 ±20.3	Time	.676	.395	.02	.11
	E	70.5 ±15.4	66.2 ±19.0	70.0 ±17.9	G x T	.943	.191	.01	.09
	Time Mean	71.1 ±18.6	69.2 ±20.0	70.9 ±17.5					
General Health	HP	77.4 ±13.7	78.2 ±16.7	79.9 ±14.2	Group	.064	1.77	.06	.35
	NCHO	65.4 ±20.5	71.4 ±19.3	71.2 ±17.2	Time	.020*	4.20	.14	.71
	E	68.9 ±15.3	74.8 ±11.9	74.6 ±14.8	G x T	.789	.427	.02	.15
	Time Mean	71 ±16	75[1,3] ±16	75[1,2] ±15					
Vitality	HP	65.8 ±13.4	69.5 ±16.9	72.7 ±11.2	Group	.267	1.35	.05	.28
	NCHO	61.9 ±16.2	68.4 (±16.5	67.4 ±14.5	Time	.031*	3.72	.13	.66
	E	61.1 ±15.0	61.8 ±14.1	65.1 ±15.6	G x T	.780	.439	.02	.15
	Time Mean	63 ±15	66[1,3] ±16	68[1,2] ±14					

Table Continues

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Social Functioning	HP	50.7 ±9.3	50.9 ±5.3	53.1 ±5.4	Group	.404	.922	.03	.20
	NCHO	46.7 ±21.9	50.7 ±6.6	47.4 ±19.4	Time	.850	.164	.01	.07
	E	50.0 ±11.0	45.4 ±13.9	49.3 ±5.1	G x T	.610	.676	.03	.21
	Time Mean	49.1 ±14.1	49.0 ±8.6	49.9 ±9.9					
Role Limitations	HP	81.4 ±32.9	91.0 ±18.3	91.1 ±11.6	Group	.094	2.48	.08	.48
	NCHO	84.9 ±29.9	83.8 ±20.7	89.3 ±15.9	Time	.963	.038	.00	.06
	E	106.4 ±35.5	94.3 ±7.4	89.5 ±13.3	G x T	.074	2.20	.08	.63
	Time Mean	90.9 ±32.8	89.7 ±15.4	89.9 ±13.6					
Mental Health	HP	74.5 ±14.4	82.5 ±16.6	90.2 ±9.6	Group	.102	2.39	.08	.46
	NCHO	74.8 ±14.1	85.7 ±11.4	87.2 ±11.1	Time	.000*	38.44	.60	1.00
	E	66.3 ±11.9	78.6 ±15.7	84.9 ±7.6	G x T	.485	.869	.03	.27
	Time Mean	72 ±13	82[1,3] ±15	87[1,2] ±9					

Note: Data represents Quality of Life- SF36 variables for the study. LSD post hoc analysis for time main effects is indicated numerically ($p< 0.05$). 1= represents $p< 0.05$ difference from baseline mean; 2= represents $p< 0.05$ difference from mean T2; 3= represents $p< 0.05$ difference from mean T3.

Beck's Depression Inventory. Table 30 summarizes findings of the total Beck's depression score. There were statistically significant findings for time effects (p=0.000) for decreased symptoms of depression but no group main effect (p=0.570), and group x time interaction (p=0.077) with this psychological questionnaire. The mean percent change over time for this variable was as follows: HP -44.5 ± 53.8%, NCHO -30.7 ±63.5% and E -18.5 ± 70.6%. The total percent change was -30.4 ± 63.1%.

Table 30. *Beck's Depression Inventory*

Beck's Depression Inventory	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Total Score	HP	4.4 ±.3.4	4.9 ±5.8	2.8 ±2.9	Group	.478	.749	.03	.17
	NCHO	6.0 ±4.3	5.5 ±6.4	4.3 ±5.4	Time	.000*	10.78	.30	.99
	E	4.7 ±4.4	3.7 ±3.0	3.2 ±2.3	G x T	.729	.51	.02	.17
	Time Mean	5.0[3] ±4.0	4.7 ±5.1	3.4[1] ±3.5					

Note: Data represents Beck's Depression Inventory variables for the study.

Body Image Questionnaire. Table 31 summarizes changes in body image over the course of the 14 week intervention. There were statistically significant time effects (p=0.020) group x time interaction (p=0.004) for Appearance Orientation. There were statistically significant time effects (p= 0.007) and group x time interaction (p=0.036) for Self Weight. The mean percent changes for Appearance Orientation (APPOR) are as follows: HP -14.4 ± 17.9%, NCHO .76 ± 26.4% and E only .09 ± 17.8%. The overall mean percent change over time for Appearance Orientation was -4.1 ± 22.1%. The mean percent changes for Self Weight are as follows: HP -33.5 ± 40.6%, NCHO -13.1 ± 24.8%, E only -14.0 ± 34.4%. The overall mean percent change over time for Self Weight was -20.1 ± 34.3%. There were no statistically significant differences among the following variables: appearance evaluation, body area satisfaction (BAS), Rosenberg self esteem scale (RSE), social physique anxiety scale (SPA) and overweight perception.

Table 31. *Body Image Questionnaire*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Physical Activity	HP	3.1 ±1.3	2.6 ±.58	2.5 ±.60	Group	.725	.324	.01	.10
	NCHO	2.7 ±1.5	2.6 ±.89	2.4 ±.50	Time	.034*	3.60	.12	.64
	E	2.9 ±1.4	2.5 ±.61	2.4 ±.59	G x T	.866	.316	.01	.12
	Time Mean	2.9 ±1.4	2.6[1,3] ±.69	2.4[1,2] ±.56					
Fitness Level	HP	2.4 ±.51	3.1 ±.43	3.1 ±.75	Group	.493	.718	.03	.17
	NCHO	2.2 ±.71	2.8 ±.69	3.0 ±1	Time	.000*	32.66	.56	1.00
	E	2.6 ±.68	3.1 ±.74	3.0 ±.75	G x T	.587	.709	.03	.22
	Time Mean	2.4[2,3] ±.63	3.0[1] ±.62	3.0[1] ±.88					
Appearance Evaluation	HP	2.7 ±.64	2.8 ±.71	2.8 ±.66	Group	.635	.458	.02	.12
	NCHO	2.4 ±.82	2.6 ±.79	2.8 ±1.2	Time	.052	3.13	.11	.58
	E	2.6 ±.69	2.8 ±.49	2.7 ±.69	G x T	.822	.381	.02	.13
	Time Mean	2.6 ±.72	2.7 ±.66	2.8 ±.85					
Appearance Orientation	HP	4.0 ±.58	3.4‡ ±.97	3.5 ±.89	Group	.731	.315	.01	.10
	NCHO	3.9 ±.72	3.7 ±.81	3.8 ±.67	Time	.020*	4.22	.14	.72
	E	3.7 ±.77	3.9Ψ ±.61	3.7 ±.87	G x T	.004*	4.13	.14	.91
	Time Mean	3.9 ±.69	3.7[1,3] ±.80	3.6[1,2] ±.81					
Body Area Satisfaction	HP	2.7 ±.54	2.4 ±1.4	2.3 ±.1.4	Group	.830	.187	.01	.08
	NCHO	2.4 ±..95	2.3 ±.1.2	2.7 ±.1.0	Time	.871	.139	.01	.07
	E	2.6 ±1.0	2.8 ±..48	2.4 ±1.2	G x T	.243	1.39	.05	.42
	Time Mean	2.6 ±.83	2.5 ±1.0	2.5 ±1.2					

Table Continues

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Overweight Perception	HP	2.8 ±.89	2.3 ±1.4	2.5 ±.1.4	Group	.244	1.45	.05	.30
	NCHO	2.9 ±.1.1	2.8 ±1.3	2.9 ±.1.1	Time	.737	.307	.01	.10
	E	2.4 ±1.2	2.7 ±.62	2.4 ±1.0	G x T	.503	.839	.03	.26
	Time Mean	2.7 ±1.1	2.6 ±1.1	2.6 ±1.2					
		2.7 ±1.1	2.6 ±1.1	2.6 ±1.2					
Self Weight	HP	4.2[Γ] ±.44	3.2 ±1.8	2.8 ±1.7	Group	.511	.680	.03	.16
	NCHO	4.1 ±1.1	3.4 ±1.6	3.7 ±1.1	Time	.007*	5.41	.18	.82
	E	3.6 ±1.4	4.1 ±.47	3.4[Ω] ±1.6	G x T	.036*	2.67	.10	.73
	Time Mean	3.9 ±.97	3.6[1,3] ±1.3	3.3[1,2] ±1.5					
Social Physique Anxiety Scale Total	HP	27.0 ±4.2	23.0 ±13.7	24.7 ±12.9	Group	.125	2.17	.08	.42
	NCHO	28.7 ±8.4	26.5 ±11.1	29.9 ±8.9	Time	.655	.427	.02	.12
	E	28.8 ±7.7	30.8 ±3.4	27.7 ±10.7	G x T	.425	.975	.04	.30
	Time Mean	28.2 ±6.8	26.8 ±9.4	27.4 ±10.8					
Rosenberg Self Esteem Scale Total	HP	28.9 ±1.7	22.8 ±13.1	24.4 ±11.8	Group	.560	.587	.02	.14
	NCHO	27.5 ±6.9	25.7 ±9.5	27.4 ±6.9	Time	.286	1.29	.05	.27
	E	27.0 ±6.9	28.7 ±1.7	25.7 ±9.2	G x T	.260	1.34	.05	.41
	Time Mean	27.8 ±5.2	25.7 ±8.1	25.8 ±9.3					

Note: Data represents Body Image Questionnaire variables for the study. LSD post hoc analysis is indicated by the following superscripts: LSD post hoc analysis is indicated by the following superscripts: Ω= represents p< 0.05 difference from mean HP T1; Ψ= represents p< 0.05 difference from mean HP T2; ∑= represents p< 0.05 difference from mean HP T3; ‡= represents p< 0.05 difference from mean E T2; Γ= represents p< 0.05 difference from mean E T3; Post hoc follow up for time main effects are indicated numerically (p<0.05). 1= represents p< 0.05 difference from baseline mean; 2= represents p< 0.05 difference from mean T2; 3= represents p< 0.05 difference from mean T3.

Profile of Mood States. Table 32 summarizes finding for the Profile of Mood States (POMS) questionnaire was completed at baseline, 10 weeks and 14 weeks. Participants completed this questionnaire based on their disposition at the time of the testing session. The results showed significant reduction in tension ($p<0.008$) and confusion ($p<0.018$) for time main effects without changes in group x time interaction ($p=0.122$ and $p=0.437$ respectively). There was a significant increase in the vigor score for time main effect ($p<0.044$) without significant changes in group x time interaction ($p=0.244$). There were no statistically significant differences in group, time or group x time effects for the variables depression, anger, fatigue or total POMS score. Therefore H_9 is rejected which states there will be statistically significant improvement in psychological status, specifically in the areas increased vigor scores ($p=0.244$) and decreased depression ($p=0.576$) as measured via questionnaires among all three groups.

Table 32. *Profile of Mood States*

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Tension	HP	-0.05 ±2.8	-0.14 ±3.3	-0.43 ±2.7	Group	.413	.900	.04	.20
	NCHO	2.1 ±3.6	0.48 ±3.4	0.10 ±2.8	Time	.008*	5.42	.18	.82
	E	1.3 ±2.3	0.49 ±2.5	-0.07 ±2.0	G x T	.492	.858	.05	.26
	Time Mean	1.1 ±2.9	0.29[1,3] ±3.9	-0.12[1,2] ±2.5					
Depression	HP	2.2 ±2.6	2.5 ±2.1	1.9 ±2.5	Group	.122	2.20	.08	.43
	NCHO	4.8 ±4.4	3.5 ±4.2	3.8 ±4.6	Time	.533	.637	.03	.15
	E	2.8 ±2.8	2.3 ±1.7	2.8 ±1.8	G x T	.576	.727	.03	.23
	Time Mean	3.3 ±3.3	2.8 ±2.7	2.8 ±2.9					

Table Coninues.

Variable	Group	T1	T2	T3	Source	Sig. (p-value)	F	ηp^2	Power
Anger	HP	1.8 ±2.1	2.1 ±1.7	2.5 ±3.0	Group	.836	.179	.01	.08
	NCHO	1.8 ±2.3	3.3 ±4.3	2.5 ±3.2	Time	.170	1.84	.07	.36
	E	2.2 ±2.3	2.3 ±1.9	2.1 ±1.9	G x T	.391	1.04	.04	.32
	Time Mean	1.9 ±2.2	2.6 ±2.6	2.4 ±2.3					
Vigor	HP	21.1 ±4.2	21.5 ±4.6	23.1 ±4.6	Group	.572	.564	.02	.14
	NCHO	19.0 ±4.5	21.4 ±5.7	21.9 ±4.5	Time	.044*	3.34	.12	.61
	E	20.7 ±5.3	20.5 ±5.4	20.5 ±4.5	G x T	.244	1.39	.05	.42
	Time Mean	20.3 ±4.7	22.7[1,3] ±5.2	21.8[1,2] ±4.5					
Fatigue	HP	6.0 ±4.7	5.4 ±5.7	4.7 ±2.8	Group	.504	.694	.03	.16
	NCHO	6.3 ±5.0	5.3 ±4.3	5.6 ±3.9	Time	.689	.376	.02	.11
	E	6.5 ±4.9	7.1 ±5.6	6.8 ±3.6	G x T	.797	.416	.02	.14
	Time Mean	6.3 ±4.9	5.9 ±5.2	5.7 ±3.4					
Confusion	HP	-.96 ±2.4	-.44 ±3.3	-1.4 ±2.2	Group	.843	.171	.01	.08
	NCHO	.34 ±3.3	-.95 ±2.7	-1.1 ±2.8	Time	.018*	4.37	.15	.73
	E	.13 ±2.8	-.75 ±1.9	-.97 ±1.8	G x T	.437	.954	.04	.29
	Time Mean	-0.16 ±2.8	-0.70[1,3] ±2.6	-1.15[1,2] ±2.3					
Profile Of Mood State Total Score	HP	30.3 ±11.5	30.9 ±10.2	30.3 ±11.5	Group	.636	.457	.02	.12
	NCHO	34.5 ±10.9	32.9 ±13.8	32.7 ±11.9	Time	.603	.511	.02	.13
	E	33.6 ±11.3	31.9 ±8.1	31.2 ±6.6	G x T	.963	.150	.01	.08
	Time Mean	32.8 ±11.2	31.9 ±10.7	31.4 ±10.0					

Note: Data represents Profile of Mood States (POMS) variables for the study. LSD post hoc analysis for time main effects is indicated numerically ($p< 0.05$). 1= represents $p< 0.05$ difference from baseline mean; 2= represents $p< 0.05$ difference from mean T2; 3= represents $p< 0.05$ difference from mean T3.

Summary of Results

Subjects in the HP experiencing significantly greater weight loss (HP -4.8 ± 3.2%, NCHO -3.0 ± 2.9%, E -1.1 ± 2.3%, p=0.001), fat mass loss (HP -10.2 ± 5.9%, NCHO -5.7 ± 4.0% and E -2.7 ± 3.9%, p=0.001), and reductions in percent body fat (HP -6.3 ± 3.5%, NCHO -3.8 ± 3.4%, and E only -2.2 ± 3.6%). Improvements were also noted in an appetite regulating hormones leptin (HP -42.1 ± 21.3%, NCHO 43.4 ± 56.1% and E .80 ± 35.1%, p=0.000). No significant changes were observed in fat free mass or resting energy expenditure. All groups experienced improvements in strength, muscular endurance, aerobic capacity, and a number of markers of health. The aforementioned results indicate that Curves exercise and weight loss program is effective in senior-aged females in promoting weight loss and favorable body composition changes. The greatest effects were seen in the HP group.

CHAPTER FIVE

Discussion

The Curves Fitness program has shown marked benefits in younger cohorts specifically in the high protein group (Kreider, 2005). The purpose of this study was to determine the effects of the Curves protocol high protein diet in elderly females aged 60-75 years in the areas of body composition, markers of health, and functional capacity. In summary, the Curves exercise and nutrition intervention was shown to be effective in weight loss, specifically fat mass, while preserving muscle mass with the greatest gains seen in the HP group. Additional body composition gains were supported by time effects in waist and hip circumference. Other gains were noted in appetite regulating hormones, specifically leptin levels with the most favorable change occurring in the high protein group. All groups experienced improvements in strength, muscular endurance, aerobic capacity, and a number of markers of health.

Sarcopenia and Dietary Protein

A loss in muscle mass contributes to the decline of metabolism in aging. Previous research supports a 15% decline in resting metabolic rate between age 30 and 80 (Calloway & Zannie, 1980; Fukagawa, Bandini, & Young, 1990; Poehlman & Horton, 1990b; Vaughan, Zurlo & Ravussin, 1991). This estimated decline corresponds with a decrease of 250 kcals burned per day. A decline in total energy expenditure is also impacted by a decrease in physical activity. Inadequate dietary protein intake is currently felt to be one of the causative factors in the progression of sarcopenia. In fact, adequate

dietary protein intake is critical to maintain the integrity, function, and health of humans by providing amino acids that serve as precursors for essential molecules that are components of all cells in the body (Academies, 2002). Protein also offers increased satiety when compared to carbohydrate which is more satiating than fat. Protein offers the highest thermic effect of all nutrients, approximately 20-30% of the energy content of proteins (Bray, & Bouchard, 2004). Dietary protein intakes of approximately 1.0 g/kg/d have been shown to maintain nitrogen balance in an elderly population however, in highly active populations studies support 1.2 to 1.4 g protein/kg/d (Chernoff, 2006). Sarcopenia is a disease that afflicts many elderly and is defined as the age-related loss of muscle mass, strength and function (Waters, D.L. et al, 2000; Vandervoort, 2001). This study intervention was able to produce statistically significant weight loss in both diet groups, but more specifically in the HP group, while maintaining fat free mass. This study has contributed additional research information that higher dietary protein can not only preserve fat free mass but produce statistically significant decreases in fat mass during an acute weight loss intervention.

Body Composition

The Curves Senior intervention study showed that with a HP diet and exercise, meaningful gains in body composition can be achieved. These findings are supportive of the benefits of a high protein diet as described above. Weight changes were significant in time main effects ($p=0.000$) and group x time interaction ($p=0.002$). The group weight loss values in kilograms from baseline to the final test session were as follows: HP -3.9 ±10.7 kg, NCHO -2.3 ± 10.7 kg ±, E only -.94 ± 10.7 kg. This study also showed there

were significant changes over time main effect (p=0.000) and group x time interaction (p=0.000) in fat mass and body fat percentage. Previous Curves research showed that during a 14 week intervention, weight can decrease by 4.5-6.4 kilograms with body fat % loss of 1-3 % (Kreider, 2005). The findings from this study are consistent with other studies in older adults that have shown a 1-4% reduction in the overall percentage of body fat with exercise training (Hagberg et al, 1983; Hagberg et al, 1989; Seals, 1984). Coupled with strength gains noted above, it is important to note that there was an upward trend in fat free mass across groups from baseline to the final test session at 14 weeks as well as stable resting energy expenditure values across groups. Statistically significant changes in the area of fat free mass may require a longer intervention period, ranging from 6-12 months (Seals et al, 1984; Kirwin et al, 1993; Kahn et al, 1990) in the elderly as compared to a younger cohort and/or a higher intensity or exercise frequency (Cox et al, 1999; Kahn et al, 1990).

Previous literature has shown that despite the statistically significant increase in fat free mass, a reduction fat mass can also be a major contender in contributing to physical capacity in aging. Research has also shown that a high body fat and high BMI value are associated with a greater likelihood of functional limitations in elderly women (Zoico, et al, 2004). A 5-year observational study called NuAge, looked at 1793 community dwelling men and women aged 68-82 years in general good health. A structural equation model was to determine the relationship between fat mass and fat free mass to physical capacity. Physical capacity was assessed by performance in walking speed and a one leg stand test. Body composition was measured via DEXA. The results showed that fat mass was significantly and inversely correlated with physical capacity

(p=0.01), as compared to no correlation with fat free mass. The researchers controlled for potential confounding variables such as physical activity, number of self-reported diseases, and age (Bouchard et al, 2007). This study supports previous research that shows exercise programs 2-3 times a week assist in maintaining fat free mass, decreasing fat mass, preserve bone density which can ultimately contribute to independence and vitality in the aging population (Seguin & Nelson, 2003).

Anthropometric Measurements

There were significant group (p=0.022) and time main (p<0.000) effect changes in waist measures during the 14 week intervention. There were no significant group x time interaction for waist circumference (p=0.095), however all groups had decreases in waist circumference. There were significant time (p<0.000) and group x time effects (p=0.012) for hip circumference reduction. The mean percent changes in waist circumference in centimeters are as follows: HP -4 ± 4%, NCHO -2 ± 3%, E only -1 ± 2%. The overall mean percent change over time was -2 ± 3%. The significant mean percent changes in hip circumference are as follows: HP -3 ± 3%, NCHO -2 ± 3% and -1 ± 2%. The overall mean percent change in hip circumference over time was -2 ± 3%. In previous Curves studies, the reduction in waist and hip measures was 1.5 -2 inches or 3.8 – 5.1 cm (Kreider, 2005).

Metabolism and Serum Hormone Markers

This study was able to show weight loss without a statistically significant reduction in resting energy metabolism while maintaining an upward trend in fat free mass and statistically significant decreases in fat mass and body fat percentage. These

findings support previous Curves research in the area of resting energy metabolism during acute weight loss intervention (Li et al, 2007; Wismann et al, 2006; Thomas et al, 2005).

In this study, elderly females had statistically significant increases in insulin levels ($p<0.000$) as well as decreased insulin sensitivity ($p< 0.000$) over the 14 week intervention. Despite the upward trend across groups, fasting insulin levels stayed on the low end of normal range for fasting insulin values for this assay (2.5-41.0 μU/mL). In women, insulin levels have been shown to increase with aging by 13% per decade (Short et al, 2003). It is also known that insulin sensitivity declines at a rate of ~ 8% per decade in both men and women (Short et al, 2003). Previous research with HOMA-IR estimates in the elderly population notes that sample size, physiologic variability of fasting insulin levels as well as the assumption that the feedback loop between the liver, peripheral sites and basal state are intact (Chang et al, 2005). Research in this area also supports a blunted age affect in insulin action in the elderly. In a study conducted by Short et al (2003), they postulated whether the effects of aerobic exercise on insulin action, diminished with aging. Their hypothesis was compared to previous studies that showed a 7-d vigorous activity program increased insulin sensitivity and muscle glucose transporter (GLUT 4) content in a similar amount in younger (22 years) and older (61 years) people (Cox et al, 1999). The aerobic exercise protocol used by Short and colleagues was consistent with current guidelines for aging adults (e.g., moderate intensities, 3 d per week over longer periods of time). Their investigation showed that there was an age dependent increase in insulin sensitivity after training despite muscle mitochondrial response in all age groups to 4 months of aerobic exercise. In conclusion, the present

study found an impairment of insulin sensitivity in aging adults. These findings are not consistent with previous Curves intervention studies in younger cohorts which showed that fasting insulin was reduced by 15% overall and insulin sensitivity improved by 19% (Kreider, 2005). The reason for this discrepancy is unclear. However, it should be noted that there was marked variability in values observed which may have contributed to present findings. In order to improve insulin sensitivity in older people, it has been hypothesized that this population could need more intense or frequent exercise sessions (Cox et al, 1999, Kahn et al, 1990). This population may also have to extend exercise interventions to 6-12 months in order to get favorable results (Seals et al, 1984, Kirwin et al, 1993, Kahn et al, 1990).

Leptin is an appetite regulating hormone that also plays a role in insulin homeostasis. The leptin values were improved over time ($p=0.001$) as well as group x time ($p=0.000$), specifically in the HP group. The reduction in leptin levels was comparable to previous Curves studies in younger cohorts for the HP group (Kreider, 2005; Moulton et al, 2006; Nassar et al, 2005). Other study findings showed time effects for adiponectin ($p< 0.033$) and ghrelin ($p<0.000$). Adiponectin, a protein secreted by adipose tissue, is present at lower levels in the obese. This study showed increases across groups during the 14 week intervention. Low levels of adiponectin have been associated with cardiovascular disease, diabetes and insulin resistance (Bray & Bouchard, 2004). Previous research on elderly males showed that resistance training and detraining may alter leptin and adiponectin responses in an intensity-dependent manner (Fatouros et al, 2005). Ghrelin also showed group x time effect interaction ($p=0.006$). Study findings for fasting ghrelin reduction in the NCHO group were consistent with previous weight

loss research that has shown weight loss increases fasting ghrelin levels (Cummings, E.E. et al, 2002; Moran et al, 2005). It is unclear why the HP and E group did not respond in a similar fashion. This finding would need further clarification in future studies. The area of research for appetite regulating hormones shows a lot of promise in better understanding the pathophysiology of obesity on a cellular level (Bray & Bouchard, 2004).

Cardiovascular Parameters

Fitness related gains were consistent with previously studied Curves cohorts in that all groups showed improvement. There were significant time effects for relative peak VO_2 (mL/kg/min) ($p=0.000$), and maximal systolic blood pressure ($p=0.002$). The mean percent change for peak VO_2 (mL/kg/min) was $10.7 \pm 23.7\%$. There were no statistically significant changes in group x time interaction for these variables ($p=0.273$ and $p=0.300$ respectively). These outcomes are consistent with previous Curves studies that showed an improvement in maximal aerobic capacity of 10% (Kreider, 2005). Improvements were also noted in the 6MWT in time ($p< 0.000$) and group x time interaction ($p=0.000$) supporting increasing in functional cardiopulmonary capacity. The magnitude of the increase in $V0_2$ in older adults has been shown to be a function of training intensity, with light intensity training eliciting minimal or no changes (Hagberg et al, 1989; Seals et al, 1984; Seals & Reiling, 1991). Previous studies have also reported cardiovascular gains with hydraulic resistance equipment in populations including patients who have undergone coronary artery bypass surgery and individuals with spinal cord injuries (Cooney & Walker, 1986; Haennel et al, 1991). Takeshima et al (2004) studied 35 men and women (age 68.3 ± 4.9) in a circuit program incorporating aerobic

exercise and hydraulic resistance exercise referred to as progressive accommodating circuit exercise (PACE) over a 12 week period. Participants exercised 3 times per week with a 10 minute warm up followed by a 30 minute exercise routine at 70% of peak heart rate. The intervention group was compared to the control (non exercise) group with gains in peak VO_2 seen with 15% improvement versus control at 4%. Additional PACE studies have shown gains in aerobic fitness (Okugawa et a, 1998; Saku et al, 1998). Previous literature in older adults has also noted benefits of aerobic exercise on cardiopulmonary capacity (Brechue & Polluck 1996; Kasch et al, 1999). Gains in cardiovascular fitness are of paramount importance in this population because cardiovascular disease poses the greatest threat as the major cause of death in older men and women (Mazeo, 1998).

Upper and Lower Body Strength Gains

There were significant changes over time in one repetition maximal effort in the bench press ($p=0.000$), bench press work volume ($p=0.027$) and leg press ($p=0.000$). These results are compared with earlier Curves intervention studies that showed an increase of 10-15% in muscular strength/endurance (Kreider et al, 2005). These results are similar to findings with previously studied hydraulic resistance programs in elderly subjects. Takeshima et al, (2004) noted chest press gains of 3-17% and leg press gains in 21% after 12 weeks of resistance training. Additional studies showing the benefits of resistance training on muscle strength in older adults have been reported by several investigators (Fiatarone & Evans, 1990; Hagerman et al, 2000; Hunter et al, 2001; Labarque et al, 2002; MaacCartney et al, 1996; Newton et al, 2002).

Functional Assessment

One of the study outcomes was to determine whether weight loss, gains in strength and changes in muscle mass had an impact on functional measures, specifically balance parameters as measured by the Neurocom® Equitest, specifically looking at 4 tests of balance. The following variables showed statistically significant time main effects over the 14 week intervention: lift up index/left leg ($p=0.009$), movement time for left ($p=0.021$) and right leg ($p=0.042$), rising index ($p=0.003$), left/right symmetry ($p=0.042$) and total composite equilibrium score ($p=0.004$). The SOT, represented by the total composite score above, is a valid and reliable measure to determine one's ability to use the three sensory systems that contribute to postural control which include: somatosensory, visual and vestibular function. This functional measure applies to daily living and the elder's ability to navigate a variety of environments such as (i.e., darkness, lack of contrast/depth cues, unstable, uneven or compliant surfaces (i.e., sandy beach, gravel driveway, boat deck, etc.) or distracting visual stimuli (busy street, crowded grocery store, etc.). In previous studies, it has been shown that exercise intervention contributes positively to the simulation of this information (Zoico et al, 2004; Tsang & Hui-Chan, 2004).

Psychological Variables

A large body of research supports the fact that obesity has an impact on physical health, emotional well-being and psychosocial functioning (Kawachi, 1999; National Institute of Health, National Heart, Lung, and Blood Institute, 1998; Pi-Sunyer, 1993; Rissanen, (1996). Previous HRQOL research shows that obese people seeking weight loss treatment are significantly more impaired than those who are not trying to lose

weight. The degree of obesity is also a factor and those suffering from more severe obesity have the poorest quality of life (Fontaine, Bartlett & Barofsky, 2000). The quality of life variables showing statistically significant improvement over time were as follows: feelings of fullness (p=0.010), general health (p=0.020), vitality (p=0.031), mental health (p=0.000), Beck's Depression Inventory (p=0.000), fitness level (p=0.000), tension (p=0.008), vigor (p=0.044) and confusion (p=0.018). A reduction was seen in appearance orientation (p=0.020 and group x time interaction p=0.004), physical activity (p=0.034), and self weight scores (p=0.007 and group x time interaction p=0.036). These findings may be unique to this age group and would need further clarification in future studies. Previous Curves interventions have shown increased scores in the areas of physical functioning, bodily pain, general health, vitality and mental health scores in conjunction with weight loss in younger cohorts (Bowden et al, 2004; Nassar et al, 2007). Harvey et al (2007) noted improvements in quality of life variables for the following: physical functioning, social functioning, vitality and mental health. In previously conducted Curves studies, improvements were also noted in the areas of body image for the following variables: appearance evaluation, body area satisfaction, and overweight preoccupation (Long et al, 2005). Davis et al (2007) noted improvements in body image variables for the following: appearance evaluation, self classified weight and appearance orientation.

Conclusions

In summary, results from the present study indicate that senior-aged women following a high protein diet while participating in a resistance-training program experience greater loss in fat mass than women following a high carbohydrate weight

loss diet. Additionally, that weight loss can be achieved in this population without reductions in fat-free mass or resting energy expenditure. Additional gains were noted in the HP group for the appetite regulating hormone, leptin ($p=0.000$). Moreover, numerous health and fitness gains were achieved among all groups. Future study in this age group could include a longer intervention with additional exercise intensity measures. Despite some of the unanswered questions and conflicting results in the field of aging, it is clear that the population of elderly adults stand to gain the greatest benefit from exercise training (Evans, 1999). Perhaps, the father of modern medicine said it best with the following timeless insight:

> *All parts of the body which have a function if used in moderation and exercised in labors which each is accustomed, become thereby healthy, well developed and age more slowly: but if unused and left idle they become liable to disease, defective in growth and age quickly Hippocrates, c. 450 B.C.* (Ferrucci & Simonsick, 2006).

APPENDIX

Application to the Baylor IRB
For Review of Research/Activity Proposal

Part 1: Signature Page

1. Name Richard B. Kreider, PhD, FPC, FACSM, FASEP
2. Email Address (optional) Richard_Kreider@baylor.edu
3. Complete Mailing Address P.O. Box 97313
4. Position Professor & Chair
5. Faculty Advisor (if researcher is Graduate Student) _____
6. Department/School HHPR
7. Telephone # x4003 FAX # x3527
8. Are you using subjects in research (Y or N) Y or in teaching exercises (Y or N)?
9. Title of the research project/teaching exercise:

   Effects of the Curve for Women® Fitness and Weight Loss Program on Body Composition, Metabolism, Functional and Exercise Capacity in Elderly, Sedentary, Overweight Females

10. Please return this signed form along with all the other parts of the application and other documentation to the University Committee for Protection of Human Subjects in Research; Dr. Matt Stanford, Chairman, Baylor University, P.O. Box 97334, Waco, Texas 76798-7304. If you have questions, or if you would like to see a copy of the OHRP Report on protection of human subjects in research, contact Dr. Stanford at extension 2961.

10-25-06
Signature of Principal Investigator — Date

_____
Signature of Faculty Advisor (required if researcher is a Graduate Student)

Departmental Review: _____
Department Chair or the Chair's Designate

Part 2: Introduction & Rationale

The Curves International fitness and weight loss program has become a very popular means of promoting health and fitness among women. Over 3 million women belong to some 8,000 Curves centers in the United States. The program involves a 30-minute circuit training program involving use of seven bidirectional hydraulic exercise machines that trains all major muscle groups interspersed with eight calisthenics type exercises designed to maintain an elevated heart rate and increase energy expenditure. For members wishing to lose weight, the program recommends following a short caloric restricted diet (1,200 kcals/day) designed to promote weight loss followed by a moderately caloric restricted diet (1,600 kcals/day) that is designed to promote a gradual reduction in body fat. The diet recommends one of two types of macronutrient manipulations based on initial dietary practices and response to a carbohydrate tolerance questionnaire. Since resting energy expenditure (REE) decreases during periods of caloric restriction and the reduction of REE has been implicated as a contributor to weight regain, the program recommends intermittent periods of increased caloric intake designed to normalize hormone levels and REE. This program is designed to promote fat loss and improve fitness without maintaining a very low calorie diet (i.e., ≤ 800 kcals/day) that is often used in weight loss trials. Additionally, it is designed to decrease the incidence of participants experiencing a weight regain once their weight goals have been achieved. The Exercise & Sport Nutrition Lab has been conducting extensive studies on the efficacy of the Curves for Women program. Preliminary results have shown that the Curves program is highly effective in promoting weight loss, improving markers of health, and improving fitness. Further, that the exercise and diet program served to increase bone density by a small but statistically significant amount. While these results are promising, additional research is needed to evaluate the effects of the Curves program in various populations who may benefit. The purpose of this study is to determine the efficacy of senior aged women participating in the Curves fitness and weight loss program on body composition, fitness, functional capacity, and health markers.

Part 3: Methodology

Participants

Approximately 60 sedentary, overweight female participants (BMI > 27) between the ages 60 to 75 will participate in this study. Participants will be medically cleared by their personal physician and will not be allowed to participate in this study if any have any uncontrolled metabolic disorders including known electrolyte abnormalities; heart disease, arrhythmias, diabetes, or thyroid disease; hypertension, hepatorenal, musculoskeletal, autoimmune, or neurological disease; if they have recently begun taking thyroid, hyperlipidemic, hypoglycemic, anti-hypertensive, or androgenic medications and are not medically stable; and/or, if they have taken ergogenic levels of nutritional supplements that may affect muscle mass (e.g., creatine, HMB),

anabolic/catabolic hormone levels (e.g., DHEA), or weight loss (e.g., thermogenics) within three months prior to the start of the study. The only exception will be if the prospective participant has a medical condition or history that the participant's personal physician feels is controlled and therefore would not be a limitation for them to participate in the study. Participants meeting eligibility criteria will be informed of the requirements of the study and sign informed consent statements in compliance with the Human Participants Guidelines of Baylor University and the American College of Sports Medicine. Participants will be required to obtain clearance to participate in the study from their personal physician before participating in baseline assessments.

Study Site

All testing will be conducted in the Exercise & Sport Nutrition Laboratory (ESNL) and/or the Exercise Physiology Lab in the Department of Health, Human Performance, and Recreation at Baylor University. Exercise training will be conducted at the Student Life Center at Baylor University.

Experimental Design

Table 1 shows the general research design and time course for assessments. The independent variable will be the exercise and type of diet. Dependent variables will include: estimated dietary energy intake; standardized quality of life (SF-36), body image, and eating satisfaction inventories; body composition, bone density, and body water assessment; hip and waist anthropometric measurements; resting energy expenditure (REE), Equitest balance and functional capacity measures, fasting clinical blood profiles (substrates, electrolytes, muscle and liver enzymes, red cells, white cells, insulin, leptin, and lipogenic enzymes); maximal cardiopulmonary exercise capacity; 6 minute walk test and isotonic strength testing.

Entry and Familiarization Session

Participants expressing interest in participating in this study will be interviewed on the phone to determine whether they appear to qualify to participate in this study. Participants believed to meet eligibility criteria will then be invited to attend an entry/familiarization session. During this session, participants will sign Informed Consent Statements and complete personal and medical histories. Participants will be required to obtain medical clearance from their personal physician prior to participating in baseline assessments. Once medical clearance is obtained, participants will be familiarized to the study protocol via a verbal and written explanation outlining the study design. This will include describing the training and dietary program, familiarizing the participants to the tests to be performed, and practicing the bench press/leg press strength tests and Equitest procedures. Participants will then be given an appointment time to perform baseline/pre-supplementation assessments.

Baseline Testing

Following the familiarization/practice session, the participants will record all food intake on dietary record forms for four days (4-d). Participants will be instructed to refrain from exercise for 48 hours and fast for 12-hours prior to baseline testing. Participants will then report to the ESNL for body composition and clinical assessments. Once reporting to the lab, subjects will complete the SF-36 quality of life (QOL) inventory, the Profile of Mood States (POMS) Psychological Inventory, the Beck Depression Inventory, the Occupational Strain Questionnaire, an appetite/eating satisfaction questionnaire and medical history forms, Participants will then be weighed, have total body water determined by bioelectrical impedance (BIA), and have body composition determined using a Discovery W Dual Energy X-ray Absorptiometer (DEXA). Participants will then have hip and waist measurements determined. Following these assessments, participants will have resting energy expenditure (REE), heart rate, and blood pressure determined using standard procedures. Participants will donate approximately 20 ml of fasting blood using venipuncture techniques of an antecubital vein in the forearm according to standard procedures. Blood samples will be run in the EBNL to run clinical chemistry profiles (glucose, total protein, blood urea nitrogen, creatinine, BUN/creatinine ratio, uric acid, AST, ALT, CK, LDH, GGT, albumin, globulin, sodium, chloride, calcium, carbon dioxide, total bilirubin, alkaline phosphatase, triglycerides, cholesterol, HDL, LDL) and whole blood cell counts (including hemoglobin, hematocrit, red blood cell counts, MCV, MCH, MCHC, RDW, white blood cell counts, neutrophils, lymphocytes, monocytes, eosinophils, baosphils). In addition, serum samples will be assayed for insulin, leptin, ketones, and lipogenic hormones and substrates. Participants will then perform 1 repetition maximum lifts on the bench press and leg press to assess strength. Finally, participants will perform a series of tests on the Equitest, a 6 minute walk test, maximal cardiopulmonary exercise stress test to assess aerobic capacity and anaerobic threshold.

Randomization and Dietary Intervention

Table 2 presents the exercise and dietary intervention protocol to be employed in the study. Participants will be randomized into one of three groups based on the Curves for Women® exercise and diet plan protocol [1]. The groups will include: 1.) Exercise + High Carbohydrate/Low Protein Diet (LCD III); 2.) Exercise + Low Carbohydrate/ High Protein (LCD I), and, 3.) a non-diet/ exercise Control group. Participants with be randomized between the three groups. Participants will maintain the Phase I diet for one week. Participants will then follow a 14 week exercise and dietary intervention program according the protocol described in Table 2. Our previous research has shown that this 14-week program promotes a 10 – 15 lbs weight loss. Once the 10-week diet phase is completed, subjects will consume a high carbohydrate, moderate protein, and low fat diet (NCD) consisting of 2,100 kcal/day in order to maintain weight loss. Subjects will be

instructed to follow the 2,100 kcals/day diet until such time (if any) that they gain 3 pounds in body weight. If they do, they will be instructed to follow the 1,200 kcals/day Phase I diet for 2-5 days until the weight is lost. Subjects will be asked to follow a diet plan developed by a registered dietitian that adheres to the macronutrient intake described in Table 2.

Training Protocol

Participants randomized to participate in an exercise program will participate in the Curves 30-minute fitness program three times per week throughout the investigation. This will involve performing seven to ten hydraulic resistance exercise machines involving bidirectional resistance that work all major muscle groups interspersed with floor-based callisthenic exercises design to maintain an elevated heart rate. The Curves equipment is located on the third floor of the Student Life Center (SLC). Research assistants will monitor exercise sessions and record attendance.

Assessment Schedule

Table 1 describes the assessment schedule to be used in the study. The assessment schedule is designed to be able to evaluate the effects of each main dietary intervention on diet, body composition, energy expenditure, and metabolism. Participants will report to a research assistant on a weekly basis throughout the study to answer a questionnaire regarding side effects and health status. Participants will record 4-day dietary records during weeks 0, 7 and 14. Participants will repeat all baseline assessments at weeks 7 and 14 of the study (excluding the maximal treadmill test at week 7). These tests will determine how the exercise and dietary interventions affect QOL, body composition, metabolism, functional capacity, balance and exercise capacity. Additionally, comprehensive analysis of blood samples will provide information on clinical safety of the program.

Data Analysis

Multivariate Analysis of variance (MANOVA) for repeated measures will be used to analyze data. Data will be considered statistically significant when the probability of type I error is 0.05 or less. If a significant group, treatment and/or interaction alpha level is observed, least significant differences (LSD) post-hoc analyses will be performed to determine where significance was obtained. Power analysis of the design indicates that an n-size of 20 per group yields high power (>0.8) for delta values of 0.75 to 1.5.

Research Team

Richard B. Kreider, PhD, EPC, FACSM. Dr. Kreider is the Professor and Chair of the Department of Health, Human Performance, & Recreation at Baylor University. Dr. Kreider is an internationally recognized exercise scientist and is past President of the American Society of Exercise Physiologists. He has conducted a vast amount of research primarily focusing on the role of exercise and nutrition and health and performance. Dr. Kreider will serve as the supervising investigator in coordinating the conduct of the study.

Melyn Galbreath, CNP. Ms. Galbreath is a doctoral candidate and will serve as a co-investigator in the study. She currently serves as the research nurse for the ESNL and Center for Exercise, Nutrition & Preventive Health Research (CENPHR).

Rafer Lutz, PhD. Dr. Lutz is the Assistant Professor and Graduate Program Director in the Department of HHPR at Baylor University. Dr. Lutz will assist in auditing data entry, statistical analysis, and manuscript preparation.

Darryn Willoughby, PhD. Dr. Willoughby serves as an Associate Professor of Exercise Biochemistry and Molecular Physiology in the Health, Human Performance, & Recreation at Baylor University.

***Rodney Bowden, PhD*.** Dr. Bowden serves as an Associate Professor of Health in the Department of Health, Human Performance, & Recreation at Baylor University. Dr. Bowden will supervise quality of life and eating satisfaction questionnaires.

Lori Greenwood, PhD, ATC. Dr. Greenwood currently serves as an Associate Professor of Sports Medicine and Athletic Training in the Department of HHPR at Baylor University. Dr. Greenwood will assist in providing medical supervision for participants involved in the study.

***Chris Rasmussen, MS, CSCS, EPC, MX*.** Mr. Rasmussen serves as research coordinator in the ESNL. He will be responsible for day to day scheduling and testing for this study.

Ronald Wilson, MD. Dr. Wilson serves as medical supervisor for the ESNL.

Research Assistants. Research assistants and a research nurse will be assigned to assist in data collection and analysis. Additional research assistants will supervise training sessions.

Registered Dietitian. The registered dietitian (RD) will develop meal plans according to the macronutrient intake goals described in Table 2. The RD will also supervise analysis of nutritional records and assist in conducting resting energy expenditure assessments.

Procedures

Medical Monitoring. Interested participants will be invited to familiarization sessions. During this time, participants will sign consent forms and complete medical history information. Participants will then undergo a general exam to determine whether the participant meets entry criteria to participate in the study. This exam will include evaluating the medical and training history questionnaires and performing a general physical examination according to ACSM exercise testing guidelines [2]. Based on this examination, a recommendation will be made by a registered nurse on whether the participant meets entry criteria and may therefore participate in the study. Participants who meet entrance criteria must obtain a signed letter of medial clearance from their personal physician provided by HHPR at Baylor University. A medical doctor along with exercise specialists certified in CPR will supervise participants undergoing exercise assessments. A telephone and an automated electronic defibrillator are located in the laboratory in case of any emergencies and there will be no less than two researchers working with each participant during testing sessions. In the event of any unlikely emergency one researcher will check for vital signs and begin any necessary interventions while the other researcher contacts Baylor's campus police at extension 2222. Instructions for emergencies are posted above the phone in the event that any other research investigators are available for assistance. Participants will be informed to report any unexpected problems or adverse events they may encounter during the course of the study to Richard B. Kreider, PhD, EPC or Chris Rasmussen, MS, MX, EPC, CSCS. If clinically significant side effects are reported, the participants will be referred to discuss the problem with the research nurse (currently Melyn Galbreath, CNP) or Lori Greenwood, PhD, ATC who is an Associate Professor of Athletic Training at Baylor University. If deemed necessary, Dr. Greenwood or Ms. Galbreath will refer the participant to Ron Wilson, MD for medical follow-up. Dr. Wilson is one of the Sports Medicine physicians for Baylor University and is an adjunct Professor in the Department of HHPR. He has agreed to provide medical support and consultation for this study and to our lab. Dr. Wilson will evaluate the complaint and make a recommendation whether any medical treatment is needed and/or whether the participant can continue in the study. If Dr. Wilson feels medical follow-up is necessary, the participant will be referred to obtain medical treatment from their personal physician. This is a similar referral/medical follow-up system that Baylor athletes are provided with the exception that participants in this study will not be provided medical care. New findings and/or medical referrals of unexpected problems and/or adverse events will be documented, placed in the participants research file, and reported to the Baylor IRB committee.

Dietary Inventories. Participants will record all food and fluid intake on dietary record forms during the week prior to the testing session day, recording 3 week days and one weekend day in order to standardize nutritional intake.

Participants will follow the guidelines detailed in table 2 and recordings will be assessed using the Food Processor III Nutrition Software.

Psychometric Assessments. Participants will complete the SF-36 Quality of life (QOL) inventory [3], the impact of weight on QOL Life questionnaire [4], body image and esteem inventories, Occupational Strain Questionnaire (8), the Profile of Mood States (POMS) psychological inventory [5], the Beck Depression Inventory [6] and an appetite/eating satisfaction questionnaire. Following the study, Participants will be asked to complete a post-study questionnaire to assess impressions about the Curves fitness and weight loss program.

Resting Energy Expenditure Assessment. Resting energy expenditure assessments will be made according to standard protocols using the Parvo Medics TrueMax 2400 Metabolic Measurement System (Sandy, UT). This will involve the participants lying down on an exam table, having a light blanket placed over them to keep warm and inserting ear plugs in their ears to reduce distractions. A see through metabolic canopy will then be placed over the participant's neck and head so that metabolic measurements can be obtained. The participant will lie motionless without going to sleep for 15-minutes. Metabolic measurements will then be obtained to determine resting oxygen uptake and energy expenditure.

Resting Heart Rate & Blood Pressure. Heart rate will be determined by palpitation of the radial artery using standard procedures [2]. Blood pressure will be assessed in the supine position after resting for 5-min using a mercurial sphygmomanometer using standard procedures [2].

***Body Composition Assessments*.** Participants will undergo body composition tests in the ESNL. Prior to each assessment, height will be measured using standard anthropometry and total body weight will be measured using a calibrated electronic scale with a precision of +/-0.02 kg. Total body water will then be estimated using a XItron 4200 Bioelectrical Impedance Analyzer (*San Diego, CA*) which measures bio-resistance of water and body tissues based on a minute low energy, high frequency current (500 micro-amps at a frequency of 50 kHz) transmitted through the body. This analyzer is commercially available and has been used in the health care/fitness industry as a means to assess body composition and body water for over 20 years. The use of this device has been approved by the Food and Drug Administration (FDA) to assess total body water and the current to be used has been deemed safe [7]. This is measured through four electrodes placed on the body: one electrode will be placed on the posterior surface of the right wrist, in between the radial and ulnar styloid processes (wrist bones), another electrode will be placed on the posterior surface of the right hand at the distal base of the second metacarpal; the third electrode will be placed on the anterior surface of the right foot at the distal end of the first metatarsal. Participants will lie on a table in the supine position and electrodes will be connected to the analyzer. After the participant is connected, age, gender,

weight, height, and activity level are entered into the unit by the technician. After the unit has measured the resistance, which takes approximately 30 seconds, the unit then calculates total body water and body water percent.

Body composition/bone density will then be determined using a calibrated Discovery W dual-energy x-ray absorptiometry (DEXA) by qualified personnel with limited x-ray technology training under the supervision of Richard B. Kreider, PhD, MX. The DEXA body composition test will involve having the participant lie down on their back in a standardized position in a pair of shorts/t-shirt or a gown. A low dose of radiation will then scan their entire body for approximately six (6) minutes. The DEXA segments regions of the body (right arm, left arm, trunk, right leg, and left leg) into three compartments for determination of fat, soft tissue (muscle), and bone mass. Radiation exposure from DEXA for the whole body scan is approximately 1.5mR per scan. This is similar to the amount of natural background radiation a person would receive in one month while living in Waco. The maximal permissible x-ray dose for non-occupational exposure is 500 mR per year. Total radiation dose will be less than 5mR for the entire study.

Blood Samples. Participants will fast overnight for twelve (12) hours and then donate approximately 4 teaspoons of fasting venous blood (20 milliliters). Blood samples will be obtained using standard phlebotomy procedures using standard sterile venipuncture of an antecubital vein by laboratory technician's trained in phlebotomy in compliance with guidelines established by the Texas Department of Health and Human Services. The phlebotomists and lab technicians will wear personal protective clothing (gloves, lab coats, etc.) when handling blood samples. Participants will be seated in a phlebotomy chair. Their arm will be cleaned with a sterile alcohol wipe and sterile gauze. A standard rubber tourniquet will then be placed on the brachium. An antecubital vein will be palpated and then a 23 gauge sterile needle attached to a plastic vacutainer holder will be inserted into the vein using standard procedures. Three serum separation vacutainer tubes (red tops) and one EDTA vacutainer tubes (purple top) will be inserted into the vacutainer holder for blood collection in succession using multiple sample phlebotomy techniques. Once samples are obtained, the vacutainer holder and needle will be removed. The needle will be discarded as hazardous waste in a plastic sharps container. The site of the blood draw will then be cleaned with a sterile alcohol wipe and gauze and a sterile Band-Aid will be placed on the site. The blood collection tubes will be labeled and placed in a test tube rack. Laboratory technicians (who have received blood borne pathogen training and will be wearing personal protective clothing) will centrifuge the serum samples, transfer serum into labeled serum storage containers, and prepare samples for shipment or storage into a refrigerator or freezer for subsequent analysis. Serum and whole blood samples will be processed in the Exercise Biochemistry Nutrition Lab (EBNL) for assay of a standard clinical chemistry profile (glucose, total protein, blood urea nitrogen, creatinine, BUN/creatinine ratio, uric acid, AST, ALT, CK, LDH, GGT, albumin, globulin, sodium, chloride, calcium, carbon dioxide, total bilirubin, alkaline phosphatase, triglycerides,

cholesterol, HDL, LDL) and whole blood cell counts (including hemoglobin, hematocrit, red blood cell counts, MCV, MCH, MCHC, RDW, white blood cell counts, neutrophils, lymphocytes, monocytes, eosinophils, baosphils) in order to evaluate markers of catabolism and clinical safety of the supplementation protocol. Serum microcentrifuge samples will be assayed for insulin, leptin, lipogenic enzymes, and markers of bone metabolism/absorption using standard ELISA and spectrophotometric techniques in the EBNL at Baylor University. Analysis of these blood parameters will determine the exercise and dietary intervention on general markers of clinical health status, insulin and markers of fat deposition.

Snack. Due to the length of the session all participants will ingest a snack after the REE and lab specimen collection that is equal in caloric amount as well as macronutrient percentages.

Cardiopulmonary Exercise Tests. Cardiopulmonary exercise tests will be performed in accordance to standard procedures described by the American College of Sports Medicine's (ACSM) *Guidelines for Exercise Testing and Prescription* [2]. A physician and nurse will be present for the stress test. This will involve preparing the participant's skin for placement of 10 ECG electrodes. Electrode sites will be cleansed with a sterile alcohol gauze using a circular motion. The site will be allowed to air dry or will be dried with a gauze pad. Electrodes will then be placed on the right subclavicular fossa (RA), left subclavicular fossa (LA), right abdomen (RL), left abdomen (LL), 4^{th} intercostals space at the right sternal border (V1), 4^{th} intercostals space at the left sternal border (V2), equidistant between V2 and V4 (V3), 5^{th} intercostal space at the midclavicular line (V4), 5^{th} intercostal space at the anterior axillary line (V5), and 5^{th} intercostals space at the axillary line (V6) of the chest. The participant will then be attached to a Quinton 710 ECG. Resting blood pressure, heart rate, and a 12-lead ECG will be obtained. The exercise specialist will then review the 12-lead ECG to ensure that no contraindications for exercise testing are apparent based on the ACSM guidelines. Participants will then stand on the treadmill. A sterile mouthpiece attached to a head harness will be secured on the participant. A nose clip will then be placed in the participant's nose. Resting expired gases will be collected using the Parvo Medics 2400 TrueMax Metabolic Measurement System. Once the participant is ready to begin the test protocol, they will straddle the treadmill with both legs while the treadmill is turned on at a speed of 1.7 mph and at a 0% grade. The participant will then use one foot to repeatedly swipe the belt in order to gauge the speed of the motion. Once the participant is familiar with this speed, the participant will step onto the belt while still gripping the handrail with both hands. Once the participant becomes comfortable walking on the treadmill, he/she will let go of the handrail and begin walking freely. The participant will then perform a standard symptom-limited Modified Bruce treadmill maximal exercise test [2].

The participant will be encouraged to exercise to their maximum unless the participant experiences clinical signs to terminate the exercise test as stated by the ACSM's *Guidelines for Exercise Testing and Prescription* (i.e., angina, dyspnea, dizziness, a decline in systolic blood pressure, dangerous dysrhythmias [increasing or multi-form premature ventricular contractions, ventricular tachycardia, supraventricular tachycardia, new atrial fibrillation, or A-V block], lightheadedness, confusion, ataxia, cyanosis, nausea, excessive rise in systolic blood pressure over 250 mmHg or diastolic over 120 mmHg, chronotropic impairment, failure of the monitoring system, or other signs or symptoms for terminating the test). The test may also be terminated at the request of the participant. Once the exercise test is complete, the participant will observe a 3-6 minute active recovery period followed by a 3-6 minute seated recovery period. The normal exercise time to maximum of the Modified Bruce treadmill protocol for untrained women is typically between 9-12 minutes (near the completion of stage III or just entering stage IV). Heart rate (HR), ECG tracings, and expired gases will be monitored continuously throughout the exercise test. Blood pressure (BP) and ratings of perceived exertion (RPE) will be obtained toward the end of each stage. Participants will be asked to report any unusual signs or symptoms to the exercise specialists during the exercise test. These tests will determine maximal aerobic capacity and anaerobic threshold to determine the effects of the exercise training on fitness and exercise capacity.

Six Minute Walk Test (6MWT). 6MWT will be conducted using a standardized protocol utilizing a flat surface of 100-foot distance marked by colored tape in the ground. Participants will be told to walk as far as possible for six minutes without running or jogging. Each minute the technician will tell the participant "you are doing well or keep up the good work". Participants may be allowed to stop and rest during the test but must resume walking as soon as they are able to do so. The tester will use a mechanical lap counter to count the number of laps completed. An electronic buzzer will sound when the six minute limit has ended.

***Strength Tests*.** All strength/exercise tests will be supervised by certified lab assistants experienced in conducting strength/anaerobic exercise tests using standard procedures [2]. Strength testing will involve the participants performing one repetition maximum (1 RM) on the isotonic bench press and the Nebula Fitness (Versailles, OH) Olympic Power Station (#1005). Participants will warm-up (2 sets of 8 – 10 repetitions at approximately 50% of anticipated maximum) on the bench press. Participants will then perform successive 1 RM lifts starting at about 80% of anticipated 1RM and increasing by 5 – 10 lbs until the participant reaches their 1RM. Participants will then rest for 10 minutes and warm-up on the Nebula 45° Leg press (2 sets of 8 – 10 repetitions at approximately 50% of anticipated maximum). Participants will then perform successive 1RM lifts on the leg press starting at about 80% of anticipated 1RM and increasing by 10 – 25 lbs until reaching the participant's 1RM.

Equipment

Digital Scale. Total body weight will be determined using a digital scale accurate to ±0.02 kg. The scale is calibrated by placing certified 25-kg weights and balancing the scale. Other than general instructions, special skills are not required to measure body weight.

Bioelectrical Impedance Analyzer (BIA). The Xitron 4200 Bioelectrical Impedance Analyzer (*San Diego, CA*) which measures bio-resistance and body composition based on a minute low energy, high frequency current transmitted through the body from surface electrodes attached to standardized anatomical locations on the dorsal surface of the right hand and foot while the participant lies motionless in a supine position. The analyzer is calibrated internally to a standard electrical current by pressing the calibration key located on the unit. A trained research assistant will perform this procedure.

Dual-Energy X-Ray Absorptiometer (DEXA). Body composition measurements will be determined by qualified personnel (in compliance with State Regulations) using a Hologic Discover W dual energy x-ray absorptiometer (*Waltman, MA*). This system segments regions of the body (right arm, left arm, trunk, right leg, and left leg) into three compartments (i.e., bone mass, fat mass, and fat-free/soft tissue mass). Quality control (QC) calibration procedures will be performed on a spine phantom (Hologic X-CALIBER Model DPA/QDR-1 anthropometric spine phantom) prior to each testing session. In addition, weekly calibration procedures will be performed on a density step calibration phantom.

Anthropometic Measurements. Anthropometric hip and waist measurements will be determined using standard procedures with a tension-regulated tape measure. The hip to waist ratio will be examined to assess the impact of this fitness and weight loss program on cardiovascular risk.

Sphygmomanometer. Blood pressure will be assessed by auscultation of the brachial artery using a sphygmomanometer using standard clinical procedures.

Metabolic Measurements & Cardiopulmonary Exercise Tests. Resting energy expenditure and maximal cardiopulmonary measurements will be obtained using Parvo Medics 2400 TrueMax metabolic measurement system. Participants will be attached to the Quinton 710 ECG (Bothell, WA) and walk on a Trackmaster TMX425C treadmill (Newton, KS). The six minute walk test will be performed on a flat surface and timed.

Strength Testing Equipment. Participants will perform the 1 RM strength tests on the Nebula (Versailles, OH) Olympic Power Station bench press and 45° leg press hip sled. Pre-measured Olympic weights and an Olympic style bar will be used.

Equi-Test. Measurements of functional stability will be collected utilizing the Neurocom SmartEquitest® (Neurocom International, Portland, OR). The SmartEquitest® consists of a long static force plate which can measure balance and mobility.

Equi-Test Procedures. The Equi-Test testing session will last no longer than 15 minutes. Data will be collected on postural balance and mobility utilizing the following tests in order:

Sit to Stand (STS): The STS test quantifies the patient's ability to rise from a seated to a standing position. The participant will sit on a platform placed on a stationary force plate with the knees at 90 deg. of flexion. The participant will be asked to rise from the seated position to a static standing position. There will be 3 trials of the STS test. The participant will be spotted during this procedure.

Forward Step Up and Over (SUO): On a stationary force plate, the participant is instructed to step forward up on to a stable wooden box with their right leg, lift the left foot over the box and down onto the force plate back to an upright standing position. The test consists of three trials of each side. The height of the step (8" or 12") will be determined based on the participant's height and knee position. If the participant's knee flexion position exceeds 90 degrees when their foot is placed on the box, the 4-12" box will be used. The participant will be spotted during this procedure.

Limits of Stability (LOS): The LOS test is conducted on a stationary dual forceplate. The LOS quantifies the maximum distance a person can intentionally displace their center of gravity (COG), i.e., lean their body in a given direction without losing balance, stepping, or reaching for assistance. For each of 8 trials, the participant maintains their COG centered over the base of support as indicated by a cursor display on the of the COG position relative to a center target. On command, the participant moves the COG cursor as quickly and accurately as possible to a second target located on the LOS perimeter and then holds the position. The participant is allows up to 8 seconds to complete each trial for a maximum test time of 64 seconds. The participant will be spotted during this procedure.

Sensory Organization Test (SOT): The SOT consists of a sequence of 6 conditions of 3 trials lasting 20 sec. each.
Condition 1: Participant stands on a fixed forceplate with eyes open.
Condition 2: Participant stands on a fixed forceplate with eyes closed.
Condition 3: Participant stands on a fixed forceplate with eyes open while the visual surround moves in a 1:1 ratio to the participants' degree and direction of sway in order to disturb their visual field.
Condition 4: Participant stands with eyes open while the forceplate tilts anterior/posterior in a 1:1 ratio to the participant's degree and direction of sway.

Condition 5: Participant stands with eyes closed while the forceplate tilts anterior/posterior in a 1:1 ratio to the participant's degree and direction of sway.
Condition 6: Participant stands with eyes open while the forceplate tilts anterior/posterior in a 1:1 ratio to the participant's degree and direction of sway and the visual surround moves in a 1:1 ratio to the participants' degree and direction of sway.
The participant will wear a harness during this procedure to protect against falling.

Participants

Recruitment

Approximately 60 sedentary, overweight or obese female participants (BMI > 27) between the ages 60-75 will participate in this study. A recruitment flyer will be posted on campus and at area fitness centers.

Selection Criteria

Participants will not be allowed to participate in this study if they:

1. have any uncontrolled metabolic disorder including known electrolyte abnormalities; heart disease, arrhythmias, diabetes, thyroid disease, or hypogonadism; a history of hypertension, hepatorenal, musculoskeletal, autoimmune, or neurological disease;
2. are taking thyroid, hyperlipidemic, hypoglycemic, anti-hypertensive, or androgenic medications for uncontrolled medical conditions.
3. have taken ergogenic levels of nutritional supplements that may affect muscle mass (e.g., creatine, HMB), anabolic/catabolic hormone levels (e.g., DHEA), or weight loss (e.g., thermogenics) within three months prior to the start of the study.
4. report any unusual adverse events associated with this study that in consultation with the supervising physician recommends removal from the study.

Compensation or Incentives

Participants completing all familiarization and testing sessions and turning in all required materials (i.e., food and training logs) will be paid $100 (i.e., $25 for each familiarization session and experimental sessions). Participants will also be given free fitness assessments during the course of the study as described above and may receive information regarding results of these tests if they desire. If participants are Baylor students, they will not receive any academic credit for participating in this study.

Potential Risks

Participants who meet eligibility criteria will be exposed to a low level of radiation during the DEXA body composition tests, which is similar to the amount of natural background radiation a person would receive in one month while living in Waco. In addition, a very low level of electrical current will be passed through each participant's body using a bioelectrical impedance analyzer. This analyzer is commercially available and has been used in the health care/fitness industry as a means to assess body composition and body water for over 20 years. The use of the BIA and DEXA analyzers has been shown to be safe methods of assessing body composition and total body water and is approved by the FDA. Participants will donate about 4 teaspoons (20 milliliters) of venous blood three (5) times during the study using standard phlebotomy procedures. This procedure may cause a small amount of pain when the needle is inserted into the vein as well as some bleeding and bruising. The participant may also experience some dizziness, nausea, and/or faint if they are unaccustomed to having blood drawn. The exercise tests that will be performed may cause symptoms of fatigue, shortness of breath, and/or muscular fatigue/discomfort. The exercise tests may also cause short-term muscle soreness and moderate fatigue for several days following the tests. Participants may also experience muscle strains/pulls during the exercise testing and/or training program. However, exercise sessions will be conducted by trained personnel and monitored to ensure the participants follow appropriate exercise guidelines. Participants will follow a prescribed dietary regimen involving consuming 1,200, 1,600 or 2,100 calories per day during various phases of the program. In addition, several groups will ingest a high percentage of calories in the form of protein. Although the total amount of total protein is not excessive (100-220 grams/day or 1.1 - 2.3 grams/kg/day for a 95 kg female) it may be higher than the participant is accustomed to ingesting and may exceed recommended protein intake for active individuals (i.e., 1-2 grams/kg/day). As a result, participant may experience weight loss or gain, feelings of hunger or fullness, and/or changes in appetite and/or mood during various phases of the dietary intervention.

Researchers involved in collecting data represent trained, non-physician, certified exercise specialists (American Society of Exercise Physiologies Certified Exercise Physiologist, Certified Strength & Conditioning Specialists, Certified Athletic Trainers, and/or American College of Sports Medicine Health Fitness Instructor$_{SM}$, Exercise Technologist$_{SM}$, Exercise Specialists$_{SM,}$ or Program Director$_{SM}$ for Preventive and Rehabilitative Exercise Programs). All personnel involved in collecting data will be certified in CPR, which is also a condition to holding these professional certifications. A telephone and automated electronic defibrillator is in the laboratory in case of any emergencies, and there will be no less than two researchers working with participant during testing. In the event of any unlikely emergency one researcher will check for vital signs and begin any necessary interventions while the other researcher contacts Baylor's campus police at extension 2222. Instructions for emergencies are posted above the

phone in the event that any other research investigators are available for assistance.

Potential Benefits

The main benefit that the participants may obtain from this study is that if this exercise and/or dietary intervention is effective there is a possibility that they may experience increased physical fitness and improvements in body composition. The participant may also gain insight about their health and fitness status from the assessments to be performed. However, even if no individual benefit is obtained, participating in this study will help to determine the impact that elderly women who participate in the Curves for Women fitness and diet program may achieve.

Assessment of Risk

Exercise and dietary modification have been a well known means of optimizing health and fitness. Overweight women have been an underserved population. This study will help identify the role of moderate exercise and dietary interventions on health status and fitness in moderately overweight elderly women. Participants will participate in a comprehensive fitness and weight loss program. During the course of the study, they will have a number of medical evaluations and fitness tests conducted. These are well established protocols used to assess health status and fitness outcomes. Potential risks will be similar to women joining Curves for Women program but be lessened by the close monitoring that they will undergo. Consequently, it is our view that the potential benefits of participants entering this study outweigh the potential risks.

Confidentiality

Information obtained from this research (including questionnaires, medical history, laboratory findings, or physical examination) will be kept confidential to the extent permitted by law. However, according FDA regulations, records will be open to FDA representatives to review if necessary. This may include questionnaires, medical history, laboratory findings/reports, statistical data, and/or notes taken throughout this study. Records of the research may also be subpoenaed by court order or may be inspected by federal regulatory authorities. Data derived from this study may be used in reports, presentations and

publications. However, participants will not be individually identified unless they give their written consent.

Data Analysis, Presentation, & Publication

Data will be analyzed using group x time repeated measures multivariate analysis of variance (MANOVA) with SPSS for Windows Version 11 software (*SPSS Inc., Chicago, IL*). Data will be considered significantly different when the probability of error was 0.05 or less. Least significant differences (LSD) post-hoc procedures will be performed when a significant interaction was observed. Data will be presented at an appropriate scientific conference (e.g., American College of Sports Medicine, Experimental Biology, etc) and published in a peer reviewed scientific journal (e.g., Medicine & Science in Sport and Exercise, Nutrition, International Journal of Sport Nutrition and Exercise Metabolism, etc).

Statement on Conflict of Interest

Funding for this study will be obtained Curves International (Waco, TX) through a grant awarded to Baylor University Researchers involved in collecting data in this study have no financial or personal interest in the outcome of results or sponsors.

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Table 1. Overview of Research Design and Testing Schedule

Familiarization and Entry	Week 0 (T1)	Week 7 (T2)	Week 14 (T4)
Phone interview Familiarization session General exam to determine qualifications to participate in study General nutritional counseling	Dietary History QOL/Eating Questionnaire Body Mass Body Water DEXA Body Composition Fasting Blood Collection Resting BP/ECG Resting Energy Expenditure Equitest Snack 6 minute walk test Maximal Cardiopulmonary Exercise Test & ECG 1 RM Bench Press & Leg Press Participants matched according to FFM and age for random assignment into: A. High Protein/Low Fat Diet I/Exercise B. High Carbohydrate/ Low Fat Diet III/ Exercise C. Exercise only- control Initiate Curve 30- Minute Fitness Training Program	Dietary History QOL/Eating Questionnaire Body Mass Body Water DEXA Body Composition Fasting Blood Collection Resting BP & HR Resting Energy Expenditure 6 minute walk test	Dietary History QOL/Eating Questionnaire Body Mass Body Water DEXA Body Composition Fasting Blood Collection Resting BP/ECG Resting Energy Expenditure Equitest Snack 6 minute walk test Maximal Cardiopulmonary Exercise Test & ECG 1 RM Bench Press & Leg Press

Diet Period	Group	Macronutrient	grams/day	Kcals/day	Percentage of Daily Diet (%)
Phase I (1 Week)	**HP + Exercise I (n=20)** (1,200 kcals/day)	Protein Carbohydrate Fat	190 20 40	760 80 360	63 7 30
	NCHO + Exercise III (n=20) (1,200 kcals/day)	Protein Carbohydrate Fat	45 165 40	180 660 360	15 55 30
	Exercise only **Control (n=20)**				
Phase II (9 weeks)	**HP + Exercise I (n=20)** (1,600 kcals/day)	Protein Carbohydrate Fat	220 60 40	880 240 360	55 15 30
	NCHO + Exercise III (n=20) (1,600 kcals/day)	Protein Carbohydrate Fat	60 220 40	240 880 360	15 55 30
	Exercise only				

Table 2. Dietary Intervention Protocol

	Control (n=20)				
Maintenance Period (4 weeks) **2100 calories daily in each diet group unless weight gain of 3 lb.s Participant will reduce to 1200 calories for 3-5 days until additional weight is reduced**	**Diet I + Exercise (n=20)** (2,100 kcals/day)	Protein Carbohydrate Fat	78 290 70	315 1155 630	15 55 30
	Diet III + Exercise (n=20) (2,100 kcals/day)	Protein Carbohydrate Fat	78 290 70	315 1155 630	15 55 30
Exercise only Control (n=20)	**Exercise only** Control (n=20)				

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