

2009

## Effects of Dietary and Exercise Interventions On The Incidence of Metabolic Syndrome

Ricky McCoy Kirby  
*University of North Florida*

Follow this and additional works at: <https://digitalcommons.unf.edu/etd>



Part of the [Nursing Commons](#)

---

### Suggested Citation

Kirby, Ricky McCoy, "Effects of Dietary and Exercise Interventions On The Incidence of Metabolic Syndrome" (2009). *UNF Graduate Theses and Dissertations*. 200.  
<https://digitalcommons.unf.edu/etd/200>

This Doctoral Project is brought to you for free and open access by the Student Scholarship at UNF Digital Commons. It has been accepted for inclusion in UNF Graduate Theses and Dissertations by an authorized administrator of UNF Digital Commons. For more information, please contact [Digital Projects](#).

© 2009 All Rights Reserved

EFFECTS OF DIETARY AND EXERCISE INTERVENTIONS  
ON THE INCIDENCE OF METABOLIC SYNDROME

by

Ricky McCoy Kirby

This project submitted to the School of Nursing in partial fulfillment of the requirements  
for the degree of

Doctor of Nursing Practice

UNIVERSITY OF NORTH FLORIDA

BROOKS COLLEGE OF HEALTH

December 2009

Unpublished work © Ricky McCoy Kirby

**CERTIFICATE OF APPROVAL**

This project of Ricky McCoy Kirby is approved:

DATE

Signature deleted

12/8/09

\_\_\_\_\_  
Kathaleen C. Bloom

Signature deleted

12/10/09

\_\_\_\_\_  
Judith Rodriguez

Signature deleted

12/8/09

\_\_\_\_\_  
Lillia M. Loriz, Committee Chairperson

Accepted for the Department:

Signature deleted

12/8/09

\_\_\_\_\_  
Lillia M. Loriz, Director, School of Nursing

Accepted for the College:

Signature deleted

12/10/09

\_\_\_\_\_  
Pamela A. Chally, Dean, Brooks College of Health

Accepted for the University:

Signature deleted

12.18.09

\_\_\_\_\_  
Mark E. Workman, Provost and Vice President for Academic Affairs

### **Acknowledgements**

Thank you to my wife Cynthia Kirby for her love and support as well as my committee Dr. Lillia M. Loriz, PhD, GNP, Committee Chairperson, Dr. Kathaleen C. Bloom, PhD, CNM, and Dr. Judith Rodriguez, PhD, RD, FADA. Thank you also goes to Dr. Albert Lopez Jr., D.O., Lopez Internal Medicine Associates, Jacksonville, Florida, and to Margarita J. Torres, MSH Student/ Dietetic Intern, University of North Florida without whose assistance this project would have been impossible.

## Table of Contents

Acknowledgements .....	iii
List of Tables .....	vi
List of Figures.....	vii
Abstract .....	viii
Chapter One: Introduction .....	1
Purpose .....	3
Definition of Terms.....	3
Chapter Two: Review of Literature .....	5
Search Strategies.....	5
Cardiovascular Disease an Overview .....	6
Metabolic Syndrome and Cardiovascular Disease .....	6
Metabolic Syndrome and Socioeconomic Position .....	11
Nonpharmacologic Measures for Treatment of Metabolic Syndrome .....	15
Diet.....	15
Exercise.....	19
Chapter Three: Methodology .....	23
Study Design.....	23
Sample.....	23
Procedures.....	24
Practice Change .....	24
Evaluation Plan .....	25
Anthropometric Measurements.....	25
Waist Circumference .....	26
Blood Pressure .....	26
Lipoprotein Levels.....	26
Glucose .....	27
Exercise Analysis.....	27
Diet Analysis.....	28
Practice Impact .....	28
Protection of Human Subjects .....	30

Chapter Four: Results .....	31
Subject Disposition .....	31
Sample.....	31
Metabolic Components .....	32
Waist .....	33
Glucose .....	34
Systolic Blood Pressure .....	34
Diastolic Blood Pressure.....	35
High Density Lipoprotein .....	35
Triglycerides .....	36
Exercise and Diet .....	36
Exercise.....	36
Diet.....	37
Chapter Five: Discussion .....	41
Discussion .....	41
Limitations and Challenges.....	42
Sample.....	42
Metabolic Components .....	43
Diet and Exercise .....	43
Record Keeping and Meetings.....	44
Selection of Participants .....	45
Implications for Future Research.....	45
Implications for Practice .....	46
Conclusion .....	46
Appendices	
A. Review of Evidence .....	48
B. Patient Profile.....	53
C. Data Collection Form.....	54
D. Exercise Handout .....	55
E. Recommended Servings of Food Groups.....	59
References .....	60
Vita .....	62

## List of Tables

Table 1.1	Comparison of ATP III, NCEP-R, IDF, and WHO Diagnostic Criteria for Metabolic Syndrome.....	2
Table 2.1	Relative Risk and Confidence Interval by Outcome in the Gami et al. Systematic Review.....	8
Table 2.2	Metabolic Syndrome Definition Predictive of Cardiovascular Disease by Definition in the San Antonio Heart Study.....	9
Table 2.3	Metabolic Syndrome Plus Age Predictive of Cardiovascular Disease by Definition: From the San Antonio Heart Study.....	10
Table 2.4	Event Prediction by Number of Component Variables of Metabolic Syndrome in the New South Wales Study.....	12
Table 2.5	Odds Ratio and Confidence Intervals for Education Level and Metabolic Syndrome Stratified by Covariant in NHANES III.....	13
Table 2.6	Calorie Consumption and Obesity in Southern Mediterranean Countries.....	18
Table 2.7	Effect Size of Exercise on Lipoprotein Levels in Overweight/Obese Sedentary Men and Women.....	22
Table 4.1	Demographic Information for the Five Individuals Who Completed the Study.....	32
Table 4.2	Descriptive Statistics for Metabolic Syndrome Component at Baseline and Day 180.....	33
Table 4.3	Average Minutes Exercised by Participant, Time Period, and Overall Rating.....	38
Table 4.4	Dietary Compliance by Participant, Time Period, and Overall Rating.....	39
Table 4.5	Average Daily Serving Change for Each Participant by Food Group.....	40

## List of Figures

Figure 4.1	Disposition of subjects.....	32
Figure 4.2	Average waist size of participants from baseline to day 180.....	34
Figure 4.3	Average Glucose of Participants from Baseline to Day 180 .....	34
Figure 4.4	Average Systolic Blood Pressure of Participants from Baseline to Day 180.....	35
Figure 4.5	Average Diastolic Blood Pressure of Participants from Baseline to Day 180 .....	35
Figure 4.6	Average HDL Levels of Participants from Baseline to Day 180.....	36
Figure 4.7	Average Triglyceride Levels of Participants from Baseline to Day 180 .....	36



## Abstract

Metabolic syndrome is a serious health problem in the United States. The presence of metabolic syndrome significantly increases the risk of developing type II diabetes and cardiovascular disease by producing a prothrombic state. The prothrombic state that results from the clustering of several independent cardiovascular risk factors within one individual increases the risk of micro and macro vascular changes and eventually to end organ damage.

There is considerable evidence to support the serious nature of this medical condition. Medications used to treat the hypertension, diabetic, and dyslipidemia components of metabolic syndrome can be a significant drain on the monthly budget of individuals and families, especially if they do not have health insurance. Diet and exercise programs have been shown to be effective in reducing adiposity and decreasing insulin resistance. These changes in lifestyle may be adjuncts or a low cost alternative to expensive medications for some individuals. The purpose of this project was to identify the effect of an intensive dietary and exercise program on patients with metabolic syndrome.

This study even with a small sample size ( $n = 5$ ) showed that waist size, systolic blood pressure, diastolic blood pressure, and high density lipoprotein levels were trending towards levels that would remove the patient from the diagnosis of metabolic syndrome. The greatest benefit for the general population would result from intervention prior to a diagnosis of hypertension and diabetes and with medication naïve individuals. Early intervention would decrease the cost of medical treatment and hospitalizations.

## Chapter One: Introduction

Metabolic syndrome is the grouping of interrelated metabolic risk factors within a single individual. The metabolic syndrome, first described in the 1920s, has been the subject of extensive research since the mid to late 1990's (Johnson & Weinstock, 2006). This clustering of risk factors increases the risk of developing type II diabetes (DM II) and coronary heart disease (CHD) (Stone & Schmeltz, 2007). Four expert groups have developed diagnostic definitions: The National Cholesterol Educational Program's Adult Treatment Panel III (ATP III), the International Diabetes Federation (IDF), the American Heart Association/National Heart, Lung, and Blood Institute (NCEP-R), and the World Health Federation (WHO).

The ATP III, NCEP-R, and IDF use waist circumference, triglyceride level, HDL cholesterol level, blood pressure, and fasting glucose as diagnostic criteria. The WHO criteria include these same five elements as well as, microalbuminuria as a sixth factor. Thus, there is no genuine consensus within the health care community as to what components comprise metabolic syndrome (Guize et al., 2007). These varying definitions make comparing studies difficult and add confusion when diagnosing metabolic syndrome. Table 1.1 presents the diagnostic criteria for metabolic syndrome from these four organizations.

Three of five diagnostic criteria or markers are necessary to make the diagnosis of metabolic syndrome using the NCEP-R definition. Treatment should target modifiable risk factors in an effort to place the patient outside the diagnostic criteria.

Table 1.1

Comparison of ATP III, NCEP-R, IDF, and WHO Diagnostic Criteria for Metabolic Syndrome

Organization	Waist Circumference	Triglycerides	HDL Cholesterol	Blood Pressure	Fasting Glucose	Diagnostic Criteria
ATP III	Men >102 cm Women > 88 cm	Men & Women >= 150	Men < 40 mg/dl Women < 50 mg/dl	SBP >= 130 DBP >= 85	Glucose >= 110	Three of the five
NCEP-R	Men >102 cm Women > 88 cm	Men & Women >= 150, or Treatment for elevated triglycerides	Men < 40 mg/dl Women < 50 mg/dl or Treatment for low HDL	SBP >= 130 DBP >= 85 or Treatment for HTN	Glucose >= 100 or Treatment for elevated glucose	Three of the five
IDF	Men >94 cm Women > 80 cm	Men & Women >= 150, or Treatment for elevated triglycerides	Men < 40 mg/dl Women < 50 mg/dl or Treatment for low HDL	SBP >= 130 DBP >= 85 or Treatment for HTN	Glucose >= 100 or Diagnosis of diabetes	Presence of abdominal obesity and two of the remaining four
WHO	BMI > 30 kg/m <sup>2</sup> or Waist-to-hip ratio Men > 0.90, Women > 0.85	Men & Women >= 150, or Treatment for elevated triglycerides	Men < 35 mg/dl Women < 39 mg/dl	BP >= 140/90	Diabetes or Impaired fasting glucose or Impaired glucose tolerance test	Fasting glucose or Insulin resistant plus two additional criteria

\*WHO criteria also include as a sixth criteria – Microalbuminuria > 30 mg albumin/g creatinine

From: “All-cause Mortality Associated with Specific Combinations of the Metabolic Syndrome According to Recent Definitions,” by L. Guize, F. Thomas, B Pannier, K. Bean, B. Jago, & A. Bentos, (2007), *Diabetes Care*, 30, 2382.

Ideally treatment should begin prior to a diagnosis of hypertension and/or diabetes. Dietary interventions to reduce caloric intake and thereby reducing circulating plasma glucose levels and waist circumference should be undertaken as early as possible. For individuals with elevated blood pressure and/or hypertension, dietary salt reduction to help reduce or prevent hypertension is an excellent initial intervention. Aerobic exercise three to five times a week for 30 to 60 minutes has been shown to increase HDL, as well as reduce circulating plasma glucose levels, triglycerides, and minimally reduce LDL cholesterol (Carroll & Dudfield, 2004).

#### *Purpose*

The purpose of this project was to identify the effects of an intensive dietary and exercise program on patients with metabolic syndrome. Specifically, the project was to examine the effects of the program on waist circumference, blood pressure, HDL cholesterol, triglycerides, and fasting glucose.

#### *Definition of Terms*

*Metabolic syndrome.* For the purposes of this project, the diagnosis of metabolic syndrome was made based on the NCEP-R definition, that is, the presence of three or more of the five diagnostic criteria (see Table 1.1).

*Intensive dietary program.* For the purposes of this project, a dietary plan was designed for each study participant. It was designed to provide flexibility and be constructed based on Mediterranean style diet principles. The dietitian provided information on frequency of consumption of foods in specific food groups, serving sizes, and number of servings. Suggested meal and snack patterns and food lists were

determined for each participant based on local, ethnic, and personal preferences, as well as socioeconomic constraints.

*Mediterranean style diet.* For the purposes of this project, the Mediterranean style diet was defined as a diet consisting of a large amount of plant foods (i.e. fruits, vegetables, nuts, and beans), minimal amounts of processed foods, a low to moderate quantity of dairy products and less than four eggs per week. A limited amount of red meat was recommended. Wine with meals in a low to moderate amount was acceptable. Fresh fruit was recommended as a desert rather than concentrated sugars.

*Intensive exercise program.* For the purposes of this project, the intensive exercise program is defined as a minimum of 30 to 60 minutes of exercise conducted at a moderate level. The exercise can be dispersed throughout the day in no less than 10 minute segments. Individuals was urged to exercise at least three and preferably five days a week.

*Moderate physical activity.* For the purposes of this project, moderate physical activity is defined as walking briskly about 3 ½ miles per hour, hiking, gardening/yard work, dancing, playing golf while walking and carrying clubs, bicycling at less than 10 miles per hour, and weight training.

## Chapter Two: Review of Literature

This chapter contains an overview of the search strategies used for identification and retrieval of the evidence. This was followed by a brief overview of cardiovascular disease and a review of the evidence with respect to the effects of metabolic syndrome on cardiovascular disease. A discussion of the relationship between socioeconomic position and metabolic syndrome was followed by a synthesis of the evidence for non-pharmacologic interventions, the Mediterranean style diet and exercise.

### *Search Strategies*

A systematic search of CINAHL, Medline, ProQuest, and the Cochrane Library was conducted for the period January 2000 through March 2008 using the key words metabolic syndrome or syndrome X. A search of Medline for meta-analyses published in the English language returned a total of 10 items. When this search was further restricted to diet or dietary and metabolic syndrome or syndrome X, three items were returned. A search of the Cochrane Library database with these same parameters returned one Cochrane Review.

The ProQuest search, limited to full text documents published in scholarly peer-reviewed journals returned a total of 1641 items. When the search was limited by Top Journals instead of Scholarly Journals the total number of items was reduced to 504. A search of the Cochrane Library database returned 234 clinical trials.

After accounting for duplications of resources across databases, a total of 5 systematic reviews and meta-analyses were reviewed. A total of 15 studies and additional articles were also reviewed.

#### *Cardiovascular Disease: An Overview*

The U.S. Department of Health and Human Services (USDHHS, 2005) identified heart disease and stroke as the principle components of cardiovascular disease. Heart disease is the leading cause of death in both men and women in the United States and stroke is the third leading cause of death. These two components of cardiovascular disease account for nearly 930,000 American deaths each year (USDHHS, 2005). This is almost 40% of all deaths and amounts to approximately one death every 33 seconds. The burden of heart disease and stroke would be lessened considerably if the major risk factors were reduced. These risk factors include high blood pressure, high cholesterol, diabetes, physical inactivity, poor nutrition, and tobacco use.

In 2005 more than \$394 billion was the projected cost of heart disease and stroke. This includes \$152 billion in lost productivity and \$242 billion in health care expenditures. Hypertension was responsible for an additional \$60 billion in health care spending in 2005 (USDHHS, 2005). A 21% decline in coronary heart disease, a 37% decline in stroke, and a 25% decline in cardiovascular deaths would result from a reduction of systolic blood pressure by 12 – 13 mmHg maintained over a 4 year period (USDHHS, 2005).

#### *Metabolic Syndrome and Cardiovascular Disease*

Metabolic syndrome increases the risk of diabetes and cardiovascular disease even in the absence of diabetes. Gami et al. (2007), in their systematic review and meta-

analysis, identified 4,198 articles and determined that 104 were potentially relevant to their question of the association between metabolic syndrome and cardiovascular events. Of these, 67 were either cross-sectional designs or contained no data with reference to metabolic syndrome or cardiovascular outcomes and one study was rejected because it had the identical study cohort as a previously published study. This left a total of 36 articles to be included in the analysis. Diagnostic criteria varied between studies and included WHO, NCEP-R, ATP III, as well as others which were not defined.

The outcomes of interest in this review were CV event, CHD event, CV death, CHD death, and death (Gami et al., 2007). After ensuring heterogeneity between the studies, the relative risk (RR) for the five outcomes was determined to be 1.60 to 2.18 (CI 1.28-2.01 and 1.63-2.93 respectively). The RR for cardiovascular events and death were significantly different between those studies that employed the WHO and NCEP criteria as compared to the other criteria. The large inconsistencies between the findings of studies that use the WHO criteria and the studies that use the NCEP criteria could not be explained merely by the use of different obesity metrics (see Table 2.1).

Gami et al. (2007) also found that the evidence, drawn from a significant number of longitudinal studies, which included 172,573 people, indicated a significant increase in the risk of cardiovascular events and death in people with metabolic syndrome and that cardiovascular risk was a third higher for women with metabolic syndrome than for men. The authors determined that use of the WHO criteria was more precise in predicting cardiovascular events and death than the ATP III criteria. The substitution of BMI (body mass index) for other measures of obesity did not adversely affect the results.



Table 2.1

*Relative Risk and Confidence Interval by Outcome in the Gami et al. Systematic Review*

Outcome	Studies n	RR	95% CI
CV event	11	2.18	1.63-2.93
CHD event	18	1.65	1.37-1.99
CV death	10	1.91	1.47-2.49
CHD death	7	1.60	1.28-2.01
Death	12	1.60	1.37-1.92

From: "Metabolic syndrome and risk of incident cardiovascular events and death: A systematic review and meta-analysis of longitudinal studies," A. Gami, B. Witt, D. Howard, P. Erwin, L. Gami, V. Somers, et al. (2007). *Journal of the American College of Cardiology*, 49, 409.

In contrast to the findings of Gami et al. (2007), Lorenzo, Williams, Hunt, and Haffner (2007) found equal effectiveness of the IDF, ATP III, and WHO diagnostic criteria in predicting CVD in their secondary analysis of data from the San Antonio Heart Study. This was a 12-year longitudinal study of 2941 individuals between the ages of 25 and 64. The researchers hypothesized that the combination of metabolic syndrome and age (equal to or greater than 45 for men; 55 for women) could be used as a good marker for cardiovascular disease (CVD) risk. They also postulated that metabolic syndrome plus impaired fasting glucose (IFG) would be a better predictor of diabetes than either parameter alone. The researchers applied the ATP III, IDF, and WHO diagnostic criteria for metabolic syndrome. The predictive value of metabolic syndrome alone was then compared to the predictive value of the Framingham 10-year risk assessment as a means to predict CVD. The American Diabetes Association 2003 criterion for diagnosis of diabetes was used (Gami et al. (2007). The development of CVD was assessed in 2,559

of the 2,941 study participants; diabetes was assessed in 1,709 of the 2,459 non-diabetic individuals in the original study.

New onset CVD was diagnosed in 93 (8.5%) men and 63 women (4.3%) for a combined incidence of 6.1% (Lorenzo et al, 2007). Metabolic syndrome was not predictive of new CVD events in individuals with existing coronary heart disease (CHD) and/or CHD risk equivalents. In individuals who did not have CHD or CHD risk equivalents the odds ratios (OR) were similar when either the ATP III, WHO, or IDF criteria was used (see Table 2.2). Sensitivity was higher for the IDF criteria.

*Table 2.2*

*Metabolic Syndrome Definition Predictive of Cardiovascular Disease by Definition in the San Antonio Heart Study*

Definition	Odds Ratio (OR)	95% Confidence Interval (CI)
ATP III	2.00	1.33 – 3.01
IDF	1.69	1.13 – 2.54
WHO	1.73	1.12 – 2.67

From: “The National Cholesterol Education Program-Adult Treatment Panel III, International Diabetes Federation, and World Health Organization definitions of the metabolic syndrome as predictors of incident cardiovascular disease and diabetes,” C. Lorenzo, K. Williams, K. Hunt, & S. Hafner. (2007). *Diabetes Care*, 30, 9.

When metabolic syndrome and age were considered together this increased the ability to predict CVD (see Table 2.3). CVD risk predicted by metabolic syndrome alone had inferior predictive value for CVD risk when compared to the predictive value of the Framingham score.

Diabetes developed in 11.4% of the subjects. The predictive value of developing diabetes by the presence of metabolic syndrome alone was similar to the predictive value using the two hour glucose tolerance test value. All definitions had similar predictive

value for diabetes, except again IDF had increased sensitivity. Lorenzo et al. (2007) determined that an improved risk assessment for diabetes may be better accomplished by considering all individuals with glucose intolerance and or metabolic syndrome at a high risk for the development of diabetes.

*Table 2.3*

*Metabolic Syndrome Plus Age Predictive of Cardiovascular Disease by Definition: From the San Antonio Heart Study*

Definition	Men Age $\geq 45$		Women Age $\geq 55$	
	OR	95% CI	OR	95% CI
ATP III	9.25	4.85 – 17.7	4.98	2.08 – 12.0
IDF	9.55	5.09 – 17.9	4.40	1.92 – 10.1
WHO	6.47	3.30 – 12.7	5.85	2.28 – 15.0

From: “The National Cholesterol Education Program-Adult Treatment Panel III, International Diabetes Federation, and World Health Organization definitions of the metabolic syndrome as predictors of incident cardiovascular disease and diabetes,” C. Lorenzo, K. Williams, K. Hunt, & S. Hafner. (2007). *Diabetes Care*, 30, 8.

A limitation of the study was that the CVD data were obtained by questionnaire and review of death certificates. The confidence intervals were wide when predicting CVD risk in women.

Simons, Simons, Friedlander, and McCallum (2007) conducted a 16 year cohort study with 2805 individuals over the age of 60 in Dubbo, New South Wales, Australia to determine if a diagnosis of the metabolic syndrome provided additional predictive value of cardiovascular disease and total mortality in the elderly above that normally associated with the known risk factors. The researchers used the NCEP-R definition of metabolic syndrome with the exception that BMI was used instead of waist circumference, with  $29.3 \text{ kg/m}^2$  as a reference point for central obesity. Hospitalization and death records were continuously monitored and mail surveys were conducted every 2 years.

Greater than 95% of the surviving participants were traceable during the last survey (Simons et al., 2007). A total of 384 men (31%) and 536 women (34%) were diagnosed with metabolic syndrome. Of these, 211 men (55%) and 259 women (48%) had CHD, 269 men (18%) and 91 women (17%) had ischemic stroke, and total mortality was for men was 256 (67%) and for women 275 (51%). All outcomes were more frequent when metabolic syndrome was present in all age groups except for those  $\geq 80$  year-of-age, but this group was also the fewest in number (see Table 2.4). After controlling for age, metabolic syndrome was a significant predictor of CHD in both men and women. Simons et al. (2007) concluded that a diagnosis of metabolic syndrome in older people is a good predictor of coronary heart disease, stroke, and total mortality over and above any other risk factors.

#### *Metabolic Syndrome and Socioeconomic Position*

A review of studies reflecting approximately 194,000 individuals in the United States, Senegal, and Europe literature found an inverse relationship between smoking prevalence, a health behavior, and socioeconomic status (SES) (Kaplan & Keil, 1993). In 1987 the prevalence of smoking was 35.7% among non-high school graduates and 16.3% among college graduates. Decreases in smoking from 1974 to 1985 were greater among college graduates (10.1%) than those with less than a high school education (1.1%). Kaplan and Keil (1993) also found an inverse relation between SES and high blood pressure.

Table 2.4

*Event Prediction by Number of Component Variables of Metabolic Syndrome in the New South Wales Study*

Number of components	MEN			Women		
	CHD	Stroke	Mortality	CHD	Stroke	Mortality
0	1.00	1.00	1.00	1.00	1.00	1.00
1	1.84 (1.12 – 3.01)	0.94 (0.50 – 1.78)	1.41 (0.96 – 2.06)	1.55 (0.93 – 2.59)	2.14 (0.92 – 4.95)	1.03 (0.70 – 1.53)
2	1.85 (1.13 – 3.05)	1.07 (0.57 – 2.01)	1.50 (1.02 – 2.20)	1.97 (1.18 – 3.28)	1.97 (0.84 – 4.64)	1.26 (0.85 – 1.87)
3	2.83 (1.71 – 5.04)	1.01 (0.51 – 2.00)	2.15 (1.45 – 3.19)	2.42 (1.45 – 4.04)	2.12 (0.90 – 5.03)	1.23 (0.82 – 1.84)
4 or 5	3.00 (1.79 – 5.04)	1.78 (0.91 – 3.48)	2.14 (1.42 – 3.23)	3.68 (2.19 – 6.20)	3.84 (1.61 – 9.15)	2.06 (1.37 – 3.11)

*Note.* Values are hazard ratios and 95% confidence intervals.

From: “Does a diagnosis of the metabolic syndrome provide additional prediction of cardiovascular disease and total mortality in the elderly? The Dubbo Study,” L. Simons, J. Simons, Y. Friedlander, & J. McCallum, (2007). *Medical Journal of Australia*, 186, 402.

Loucks, Rehkopf, Thurston, and Kawachi (2006) found that socioeconomic position (SEP) is associated with metabolic syndrome and that the association differs by gender and ethnicity (see Table 2.5). There were a total of 11,107 participants 25 years of age or older with 5,341 men and 5,766 women. The prevalence of metabolic syndrome in this sample was 29.9% (95% CI, 27.7 – 32.3) in men and 28.4% (95% CI, 26.2 – 30.8) in women.

Table 2.5

*Odds Ratio and Confidence Intervals for Education Level and Metabolic Syndrome Stratified by Covariant in NHANES III*

Women		Years of Education				
		< 12 Years n=2166		12 Years n=1941		> 12 Years n=1659
Ethnicity	Model Adjustment	OR	95% CI	OR	95% CI	OR
All	Age, ethnicity	2.25	1.74-2.91	1.67	1.31-2.12	1.0
	Age, ethnicity, health behaviors	1.85	1.42-2.41	1.54	1.21-1.97	1.0
	Age, ethnicity, health behaviors, parity	1.77	1.39-2.24	1.46	1.16-1.84	1.0
White n=718, 1012, 952	Age, ethnicity, health behaviors, parity	1.68	1.26-2.23	1.35	1.03-1.77	1.0
Black n=504, 553, 440	Age, ethnicity, health behaviors, parity	1.10	0.68-1.78	1.42	1.06-1.90	1.0
Mexican-American n=849, 323, 186	Age, ethnicity, health behaviors, parity	1.66	1.04-2.64	1.36	0.95-1.94	1.0
Men		n=2276		n=1440		n=1659
All	Age, ethnicity	1.33	1.04-1.70	1.40	1.13-1.77	1.0
	Age, ethnicity, health behaviors	1.27	0.97-1.66	1.32	1.04-1.68	1.0
White n=738, 700, 979	Age, ethnicity, health behaviors	1.20	0.87-1.66	1.37	1.04-1.68	1.0
Black n=515, 423, 322	Age, ethnicity, health behaviors	1.01	0.63-1.62	1.02	0.69-1.51	1.0
Mexican-American n =52, 274, 250	Age, ethnicity, health behaviors	0.75	0.54-1.05	0.87	0.53-1.45	1.0

*Note.* Health behaviors alcohol consumption, smoking, physical activity, and diet:

From: "Socioeconomic disparities in metabolic syndrome differ by gender: Evidence from NHANES III," E. Loucks, D. Rehkopf, C. Thurston, & I. Kawachi, (2007). *Annals of Epidemiology*, 17, 23.

Less than 12 years of education was statistically significantly associated with an increased risk of metabolic syndrome in both men (OR 1.33;95 % CI 1.04 – 1.70) and women (OR 2.25; 95 % CI 1.74 – 2.91) (Loucks et al., 2006). When adjusted for health behaviors (dietary consumption of total fat, carbohydrates, fiber, physical activity, smoking, and alcohol consumption) the relationship remained significant for women but not for men.

Santos, Ebrahim, and Barros (2008) found similar results when investigating socio-economic and gender status and metabolic syndrome in adults in Porto, Portugal. There were 1962 participants aged 40 or older (1207 women and 755 men). The prevalence of metabolic syndrome in the study population was 22.0% using ATP III criteria and 31.8% when IDF criteria were applied. They found that metabolic syndrome was more prevalent in women verses men using both definitions, All five of the diagnostic criteria were present in 3.1% of the women and 0.6% of the men. The odds of metabolic syndrome in women increased with age and decreased with education level and social class. In men metabolic syndrome was not associated with any socio-economic indicators. The researchers hypothesized that an unfavorable socio-economic environment increases the risk of metabolic syndrome in a gender-specific manner and that men in lower socio-economic strata are more likely to have more physically demanding occupations which would increase their total caloric expenditure (Santos et al., 2008). This would be a protective mechanism for men that would prevent them from developing metabolic syndrome.

### *Nonpharmacologic Measures for Treatment of Metabolic Syndrome*

Lifestyle modification is a primary treatment modality for all of the parameters that make up metabolic syndrome. Such modifications include changes in both dietary and exercise behaviors.

*Diet.* Food consumption patterns may be related to socioeconomic status (Loucks et al., 2008). Energy dense foods are predominantly composed of sugars, fats, or refined grains are cheaper and individuals with low incomes may preferentially purchase these foods resulting in a higher caloric intake and increased risk of obesity. Simple changes in diet may decrease the incidence of metabolic syndrome. The Mediterranean style diet has been discussed as one way to facilitate a healthier life style.

The Mediterranean style diet consists of a large amount of plant foods (i.e. fruits, vegetables, nuts, and beans), minimal amounts of processed foods, fresh fruit as a desert rather than concentrated sugars, low to moderated amounts of dairy products (i.e. yogurt and cheese), less than four eggs per week, low amounts of red meat, and wine with meals in a low to moderated amount (Serra-Majem, Roman, & Estruch, 2006). There is, in general, a higher incidence of cardiovascular disease in the United States and northern European countries when compared with countries of the Mediterranean basin (France, Spain, Greece, and Italy). This difference in incidence has led to investigation of the association of diet to cardiovascular disease.

Serra-Majem et al. (2006) identified 55 clinical trials investigating this relationship, of which 12 were excluded due to language, the fact that the intervention was limited to one food product, or for methodological weaknesses, leaving 43 studies for the systematic review. The authors identified weaknesses in the review of the



evidence on the use of the Mediterranean style diet. The evidence is derived primarily from observational studies, personal reviews, and several studies were excluded from previous reviews of the Mediterranean style diet (Serra-Majem et al., 2006). These excluded studies were critical of, or did not support the use of, Mediterranean style diet raising the possibility of bias in the other analysis. In their opinion several of the excluded studies were well conducted and their outcomes valid.

Belahsen and Rguibi (2006) found that there is increasing evidence that lifestyle changes which incorporate a decrease in activity, an increase in caloric intake, and adopting a more western style diet may be contributing to the increase in obesity and diabetes in southern Mediterranean countries. They postulate that by the year 2020 71% of ischemic heart disease deaths, 75% of stroke deaths, and 70% of diabetes related deaths will occur in developing countries.

Belahsen and Rguibi (2006) determined that an increase in cardiovascular risk factors and rates of obesity in this area is linked to an increasingly sedentary way of life. There has been a decrease in physical activity and leisure time is spent watching more hours of TV per week. There is also a corresponding increase in the utilization of vehicles and activity saving appliances. The Jordan Global School-Based Student Health Survey showed that 44.6% of men and 45.2% of women did not walk or ride a bike. A study in 2002 among Moroccan women over 15 years of age found that physical inactivity appeared to play a crucial role in the development of body fat and may be a risk factor for development of metabolic syndrome (Belahsen & Rguibi, 2006).

There has been significant progress in raising food consumption per person and this increased availability of food has created a shift in what had been the standard diet in

this area of the Mediterranean. This shift in diet has created away from barley as the primary grain source and an increased consumption of wheat and livestock products. There is also a shift towards the use of vegetable oils for a dietary fat source. Belahsen and Rguibi (2006) believe that the “important point is that there has been a remarkable increase in the intake of dietary fats” (p. 1133). There has also been an approximately 1000 kcal per capita per day increase from 1965 – 2000, which exceeds the per caput energy requirements.

This shift from the traditional Mediterranean style diet to a more western industrialized diet and a more sedentary life style could explain the increases in obesity seen in this region (see Table 2.6). A move from a more rural to urban population has also been accompanied by an increase in obesity, hypertension, diabetes, and hypercholesterolaemia (Belahsen & Rguibi, 2006).

The Mediterranean dietary pattern emphasizes that fat consumption should be between 30 and 40% of an individual’s daily energy intake (Giugliano & Esposito, 2008). These fats should primarily come from monounsaturated fatty acids. There is not a single Mediterranean style diet as the dietary habits vary from country to country, but the primary characteristics of this dietary style include large amounts of plant food, olive oil as the principle source of dietary fat, fish and poultry in moderation, little red meat, and a moderate amount of alcohol usually with meals in the form of wine.

In a review of the European Prospective Investigation into Cancer and Nutrition (EPIC) study of 17,238 women and 10,589 men who were not obese at baseline, individuals with a high adherence to Mediterranean style diet had a significantly lower risk of being obese (OR 0.69, 95% CI 0.54-0.89 for women; OR 0.68, CI 0.53-0.89 for

men) (Giugliano & Esposito, 2008). When a high consumption of olive oil (46g/day) was compared with a lower consumption (6g/day) there was no association with increased weight. An inverse relationship was also observed between adherence to the Mediterranean style diet and increases in insulin resistance. Additionally, a cross-sectional analysis of 2,834 individuals in the Framingham Offspring Study showed that whole grain and cereal fiber intakes were associated with a 38% lower risk of development of metabolic syndrome (Giugliano & Esposito, 2008).

*Table 2.6*

*Calorie Consumption and Obesity in Southern Mediterranean Countries*

Country	Energy Consumption		Male Obesity %		Female Obesity %	
	1965-1967	2000-2002	2002	2005	2002	2005
Algeria	1740	2990	4.52	5.18	11.91	13.44
Egypt	2287	3318	21.98	21.98	39.34	45.46
Jordan	2152	2834	19.62	19.62	40.19	35.62
Libya	2061	3324	10.74	11.45	21.13	22.52
Tunisia	2323	3272	7.74	7.74	28.78	30.2

*Note.* Energy consumption in kcal per capita per day; obesity = BMI > 30 kgm<sup>-2</sup>  
 From: "Population health and Mediterranean diet in southern Mediterranean countries,"  
 R. Belahsen, & M. Rguibi, (2006). *Public Health Nutrition*, 9, 1133.

The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) recommends lifestyle modification by all individuals and adopting healthy lifestyles (USDHHS, 2003). Lifestyle modification is an indispensable part of the management of those with hypertension. In individuals who are overweight or obese major lifestyle modifications

have been shown to be effective in reducing blood pressure (USDHHS, 2003). The JNC 7 also recommends the use of Dietary Approaches to Stop Hypertension (DASH) eating plan (USDHHS, 2003). The DASH diet is rich in potassium and calcium, but recommends a restriction on dietary sodium, an increase in physical activity, and moderate alcohol consumption. The lifestyle modifications that reduce BP also enhance antihypertensive drug efficacy and this synergistic approach decreases cardiovascular risk. A 1,600 mg sodium DASH diet plan has similar outcomes in blood pressure reduction to single drug therapy. When combinations of two or more lifestyle modifications are initiated they can achieve even more blood pressure reduction (USDHHS, 2003).

*Exercise.* Another risk factor for metabolic syndrome that is suitable for intervention in individuals in all socioeconomic circumstance is exercise. Carroll and Dudfield (2004) performed a review of literature to determine the effects of exercise on the metabolic syndrome, insulin resistance, abdominal adipose tissue accumulation, impaired glucose regulation, atherogenic dyslipidemia, and hypertension.

Nine months of exercise training alone increases maximal aerobic capacity by 14% in obese middle-aged and older men without a significant change in bodyweight, oral glucose tolerance response, lipids, or blood pressure. Hypocaloric diets and body weight reduction also improve insulin resistance. When dietary changes or exercise induce an 8% weight loss, insulin sensitivity improves up to 60% (Carroll & Dudfield, 2004).

A regular exercise program conducted three to five times a week for 30 to 60 minutes at lower intensity than what is typical for cardiovascular fitness has shown

metabolic benefits (Carroll & Dudfield, 2004). Aerobic exercise and dietary studies found that exercise lowers blood pressure and improves glucose metabolism in obese, sedentary insulin-resistant men. This intervention reduced body fat by 21% and produced a 9% overall reduction in weight (Carroll & Dudfield, 2004). In sedentary overweight European and South Asian males and females exercise training consisting of three half-hour sessions of walking or jogging and one supervised aerobic circuit training session produced no weight change, but insulin sensitivity was improved by 40% (Carroll & Dudfield, 2004).

When blood glucose levels are higher than normal, but less than a diagnostic level for diabetes it is referred to as impaired glucose regulation. Carroll and Dudfield; (2004); reviewed the 1999 Obesity Education Initiative expert panel. This panel reviewed five RCTs that showed weight loss produced by lifestyle intervention improved fasting glucose levels when compared to controls. They reviewed three additional RCTs which were conducted in various countries with various ethnic groups. The review of these RCTs confirmed that regular exercise can prevent or delay the onset of type II diabetes in high risk groups who suffer from impaired fasting glucose.

Individuals with low levels of HDL cholesterol, hypertriglyceridemia, and a high level of small dense low density lipoprotein (LDL) have atherogenic dyslipidemia. This cluster of dyslipidemic markers has been associated with increases in CVD. The literature search revealed 65 RCTs investigating exercise and lipoprotein-lipids. Only 15 of the original 65 articles were analyzed (Carroll & Dudfield, 2004). The 15 clinical trials incorporated 20 study groups. Ten study groups were composed of male only participants, six groups were mixed male and female, and 4 groups were female only.

There were 1007 total participants with 587 randomized to the exercise intervention groups and 420 to control groups. The duration of the exercise interventions ranged from 12 to 52 weeks with a median of 39 weeks. Exercise frequency was three to five times a week with the duration being 30 to 60 minutes.

Body mass changes were reported in 12 of the 20 treatment groups and three others reported changes in BMI (Carroll & Dudfield, 2004). The mean changes in body mass in the exercise study groups ranged from between 1.5 and 1.9 kg; except that the single 12 month program produced a 4.0 kg change. All 20 study groups examined HDL-C response to exercise training alone compared with a control group with no exercise. HDL-C analysis showed an increase of 0.046 mmol/L (95% CI 0.27 – 0.65mmol/L,  $p < 0.0001$ ) (Carroll & Dudfield, 2004). Triglycerides were evaluated in 19 of the 20 groups. There was a mean reduction of triglycerides of -0.21 mmol/L (95% CI of -0.29 to -0.14,  $p < 0.0001$ ) (Carroll & Dudfield, 2004). The results of this analysis revealed that moderate to moderately vigorous regular supervised exercise training is associated with modest improvements in HDL and TG levels in a middle-age and older overweight or obese adults (see Table 2.7).

Hypertension is a well established metabolic disorder and approximately 25 to 33% of normal weight hypertensive individuals also suffer from insulin resistance. A three to nine percent reduction in weight is associated with a mean reduction of systolic and diastolic blood pressure of approximately 3.0mm Hg. Exercise training reduces blood pressure in approximately 75 – 85% of the groups with a weighted mean reduction of 10.6/8.2 mm Hg. These blood pressure reductions were noted as early as 10 weeks after commencement of the exercise program. (Carroll & Dudfield, 2004).

Table 2.7

*Effect Size of Exercise on Lipoprotein Levels in Overweight/Obese Sedentary Men and Women*

Lipoprotein Particle Type	Standardized mean difference method			Weighted mean difference method		
	Effect Size	95% CI	p-value	Effect Size	95% CI	p-value
Total Cholesterol	-0.05	-0.178, 0.08	0.50	-0.05	-0.14, 0.04	0.29
LDL-C	0.001	-0.116, 0.12	0.98	0.005	-0.07, 0.06	0.89
HDL-C	0.254	0.14, 0.37	<0.0001	0.046	0.27, 0.065	<0.0001
Triglycerides	-0.326	-0.46, -0.21	<0.0001	-0.21	-0.286, -0.14	<0.0001

From: "What is the relationship between exercise and metabolic abnormalities?" S Carroll, & M. Dudfield, (2004). *Sports Medicine*, 34, 339

This chapter has been a review of literature on the prevalence and cost of cardiovascular disease in the United States and the cause and effect relationship of metabolic syndrome and cardiovascular disease. The effect of socioeconomic position has on the prevalence of metabolic syndrome was reviewed, as well as the nonpharmacologic measures that can be employed to combat metabolic syndrome.

### Chapter Three: Methodology

This chapter includes a description of the design, setting and sample for the project and the methods and procedures for the study. This is followed by a discussion of the feasibility, data analysis plan and protection of human subjects.

#### *Study Design*

This project was the implementation of an evidence-based practice change incorporating an intensive dietary and exercise program for patients with metabolic syndrome and evaluation of the effect of that change on lipoproteins HDL-C and triglycerides, serum glucose levels, blood pressure, and waist circumference. This study was a one-group before-and-after design, with baseline data obtained on patients prior to the practice change. The study ran for six months.

#### *Setting and Sample*

The setting for the study was an internal medicine practice in a large city in the Southeastern United States. The practice has one physician and one nurse practitioner. There are approximately 3,206 patients in this practice 20% of whom would meet the inclusion criteria.

Criteria for inclusion in the study were: males and females ages 18 to 65 who met the ATP III diagnostic criteria for metabolic syndrome. Exclusion criteria were: individuals diagnosed with diabetes and those with, dietary limitations due to religious or medical conditions, or who were unable to perform the moderate exercise portion of the



study due to preexisting medical conditions. Participants, who were diagnosed with diabetes after the start of the study, were eligible to complete the study and be included in the final analysis.

### *Procedures*

Participants were recruited for 30 days from the practice location. All patients who met the inclusion criteria were considered eligible for the study. Patients who had a current diagnosis of metabolic syndrome and who consented to be in the study were re-evaluated by ATP III criteria and if they met the definition were eligible for participation. Other individuals who did not have a diagnosis of metabolic syndrome, but during the normal course of their appointments appeared to meet the criteria were evaluated by ATP III criteria and if diagnosed with metabolic syndrome they were given the option of participation during that office visit. Prior to agreeing to participate all individuals were counseled by the primary investigator regarding the diet and exercise programs.

*Practice change.* A food consumption frequency analysis was performed on all patients entering the study. A food scoring system (FSS) was utilized to provide information on frequency of consumption of foods within specific food groups.

Dietary counseling was provided to each participant at the time of the initial and each subsequent visit. The diet and exercise programs were furnished as an individualized folder/booklet. These booklets include exercise and dietary logs as well as other educational materials. Handouts/pamphlet on diet and exercise recipe booklet, sample shopping list, invitation to E-mail newsletter was provided at the initial meeting. The participants' exercise and dietary logs were reviewed at the visits on day 30, day 90, and day 180.

The exercise recommendations were based on the data reviewed earlier as well as the recommendations of the American Heart Association and the US Department of Agriculture food guide pyramid. All study participants had their current exercise practices evaluated prior to beginning the study. Each participant was then counseled by the primary investigator on an unsupervised exercise program. Weight training was also encouraged. A written exercise program was provided to each participant at the initial visit in addition to the exercise log.

#### *Evaluation Plan*

Two medical assistants were trained in all aspects of data collection and they were the only individuals except the primary investigator and a master's level dietetic intern to collect data. A complete history and physical examination was performed at the initial visit. The history included a review of social, demographic, personal, and family medical history including current dietary habits and physical activity, tobacco use, and alcohol intake. The physical exam consisted of a head-to-toe physical and included anthropometric measurements (height, weight and calculation of BMI), waist circumference, and blood pressure. Laboratory studies included lipoprotein and glucose levels.

Subsequent visits occurred at 30, 90, and 180 days. Evaluation included updating the medical history, including smoking and alcohol intake; measuring lipoproteins, fasting blood glucose, blood pressure, waist circumference, anthropometrics; analysis of dietary and exercise logs; and individual counseling based on these measurements.

*Anthropometric measurements.* Anthropometrics were obtained at each visit with the participant in light clothing and barefoot. Body weight was measured to the nearest  $\frac{1}{4}$

pound as measured on a standard standing office scale. Height was measured at the initial visit to the nearest 1/8<sup>th</sup> inch using a stadiometer. BMI was calculated using a standard BMI chart.

*Waist circumference.* Waist circumference was measured at each visit with the subject standing erect with the clothing from around the waist removed. A flexible un-stretchable tape was used, avoiding exertion of pressure on the tissue. The waist circumference was measured midway between the lower limit of the rib cage and the iliac crest with the tape level and recorded to the nearest millimeter using the same tape measure at each visit.

*Blood pressure.* Blood pressure was measured at each visit using U.S. Department of Health and Human Services (JNC 7) (2003) guidelines. The auscultatory method with a properly calibrated and validated instrument was used to measure blood pressure. The subject was seated quietly for at least 5 minutes in a chair with both feet on the floor and the arm supported at the heart level. An appropriate sized cuff with the bladder encircling at least 80% of the arm was used. Two readings were taken at least five minutes apart and the average of the two readings were used unless there was a difference in the systolic blood pressure readings of more than 6 mmHg. If a third reading was necessary the average of the two closest readings was used.

*Lipoprotein levels.* Fasting lipoprotein levels were measured at baseline, 90 days, and 180days. Lipoprotein levels (total cholesterol, triglyceride, HDL-C, and LDL-C) were evaluated using a Cholestech LDX Cholesterol Analyzer<sup>TM</sup>. The reliability of the analyzer was established per the manufactures instructions using the Cholestech optics check and liquid controls. The optics check was conducted using the analyzer check

cassette supplied with the unit. The optics check was conducted at a minimum once each day before patient sampling, when the unit was moved, or when the unit was serviced. The liquid controls were conducted at the beginning of each visit and if a different lot number or new box of cassettes was opened. The blood sample required for this evaluation was collected by finger stick.

*Glucose.* Fasting glucose levels were evaluated with an Accu-Chek Compact Plus capillary glucose meter. This glucometer does not require calibration. Coding is performed automatically when the test strip drum is placed in the glucometer. Control testing, with the provided control solution, was performed as a minimum when the test strip drum was replaced, if the meter was dropped, or if the control bottle symbol flashed on the meter display. This did not require a second finger stick, since there was ample blood from the finger stick performed for the lipoprotein analysis.

*Exercise analysis.* An exercise analysis was performed on all patients entering the study. Each participant was then counseled by the primary investigator regarding the exercise component. Participants were provided with written information regarding exercise, an exercise log, encouraged to exercise at least three (ideally five) days per week at a moderate level and to record their exercise on the exercise log. Exercise was defined as additional time during the day separate from work or other normal daily activities. The exercise component was evaluated at each visit. The exercise logs were evaluated and exercise was categorized as none (0 days per week), minimal (1-2 days per week), moderate (3-4 days per week), or maximal (more than 4 days a week). Exercise was judged as compliant or noncompliant. Participants were judged to have been compliant with the exercise component if their exercise averaged more than 135 minutes

per week (45 minutes a day for a minimum of 3 days a week) and were compliant at least 13 of the 25 weeks of the study.

*Dietary analysis.* A food consumption analysis was performed on all patients entering the study using a food scoring system (FSS). Each participant was then be interviewed and counseled by the master's level dietetic intern regarding the customized Mediterranean style diet. This customized plan was based on age, gender, weight, height, and physical activity and included suggested calories to be consumed each day, servings of grains, beans, vegetables, fruits, dairy products, healthy fats, and meats. Written information on the Mediterranean style diet was provided for each participant at the first visit along with the dietary log. At each visit the dietary logs and the FSS were reviewed to assess overall compliance as well as compliance within each food category/group. A nutrient analysis was not conducted. The FSS provided a baseline description of the participants' diet and how it related to the recommended Mediterranean style diet. The same FSS was used throughout the study to measure change and compliance over time. The master's level dietetic intern also evaluated the participants' dietary changes as they relate to the participants' perception of their progress. This was developed as a critique of the dietary portion of the project. A FFS was completed during the last visit and changes in dietary patterns were assessed in relation to the initial FFS.

#### *Practice Impact*

Current staff members were trained on and are proficient in the use of the materials to be used. A review of the material and the specific requirements of the study was conducted. Staff members were briefed on confidentiality and the study guidelines.

There was minimal fiscal impact on the practice setting. Initial participant interviews coincided with previously arranged office visits. Follow-up visits were conducted during non-office hours so as to not interfere with the operation of the clinic and no reimbursement from insurance companies was sought. The medical assistants agreed to participate without compensation for their time, but were reimbursed for fuel and a meal was provided. The total cost of intervention supplies per participant was estimated to be approximately \$.0.15 per visit (see descriptions below). This cost was borne by the practice. The total cost of miscellaneous supplies, copying, binding, folders/booklets, and computer supplies did not exceed \$300. During the implementation period, this cost was borne by the primary investigator.

The Cholestech LDX Analyzer was available in the practice site and the cost of each use was approximately \$12 per cassette per visit. The cassettes for the cholesterol analyzer are being donated by the Cholestech representative and purchased by the primary investigator out of a grant from the University of North Florida, School of Nursing. The cost of the one use lancing device is approximately \$0.02 per patient per visit. Miscellaneous supplies (cotton balls, alcohol wipes, gauze) cost approximately \$0.05 per participant per visit.

A new Accu-Chek Compact Plus capillary glucose meter was supplied by the Accu-Chek representative at no cost. The cost of the test strips was approximately \$0.95 per strip. The Accu-Chek representative also supplied the test strip drums and control solution at no cost.

*Protection of Human Subjects*

Prior to beginning recruitment of participants University of North Florida (UNF) Institutional Review Board (IRB) approval was obtained. All institutional, state, and federal regulations with respect to protection of human subjects were adhered too. If at any time possible injury either physical or psychological to a participant was suspected the action or inaction that could have caused the injury would have been immediately corrected. No actual injuries occurred. The procedures outlined by the UNF IRB would have been followed if required.

Protection of participant information was of paramount importance. After closing recruitment participants were randomly assigned a study number and all collected data was only linked to the study number. Any documents that linked a participants name or other identifying data with their study number was maintained by the primary investigator in a secured area. Any documents that would link a participants name with their study number or other study data was destroyed as soon as possible after the study was closed. Data collectors and researchers, other than the primary investigator, did not have access to the raw data until the study was ended.

## Chapter Four: Results

This chapter provides a description of the sample and the results of the analysis pertaining to outcomes. This is followed by a discussion of unintended consequences and barriers encountered.

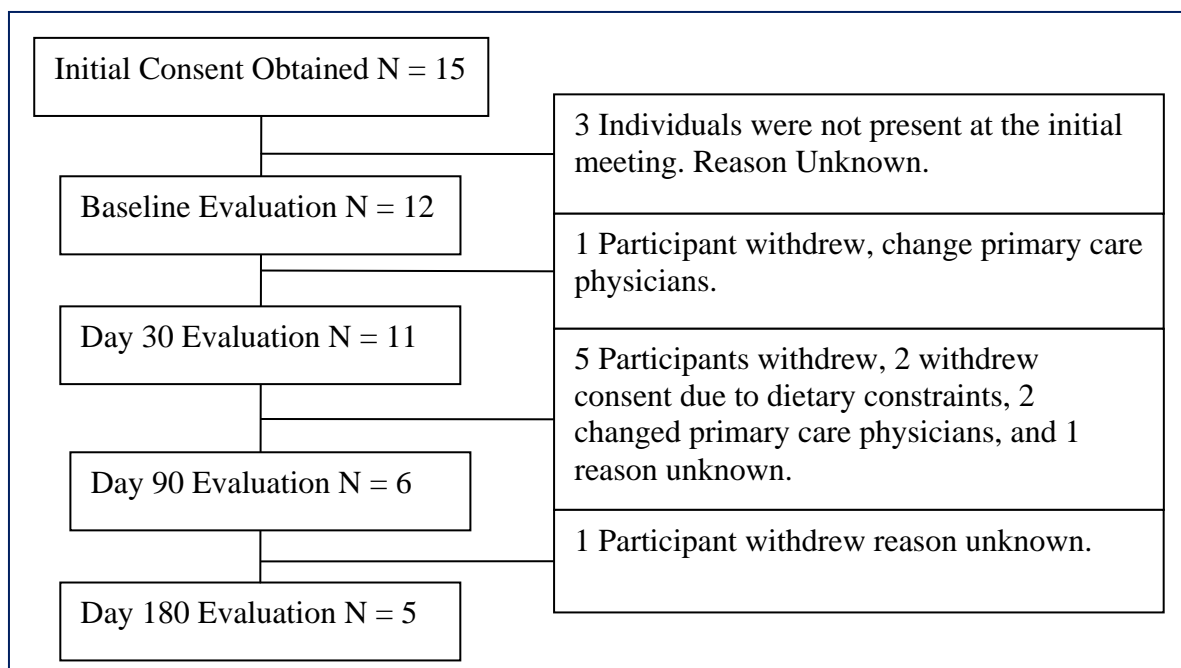
### *Subject Disposition*

During the enrolment period fifteen (15) patients who met the inclusion criteria agreed to participate in the study. The first meeting (baseline) was conducted one week after the closing of the enrolment period. Twelve of the fifteen participants were present at the first meeting and had baseline biometric measurements taken. The attrition of participants continued throughout the study period. Ten of the participants who signed consents did not complete the study. Five of the ten withdrew for unknown reasons, three withdrew due to changing primary care physicians, and 2 withdrew due to the dietary constraints. Figure 4.1 shows the disposition of subjects during the study period.

### *Sample*

Five of the original fifteen participants completed the study. All were Caucasian, three of the five were male with the youngest being 47 and the oldest being 55. Two were female and their ages were 40 and 61. Table 4.1 shows the demographic information of the five individuals who completed the study.





*Figure 4.1. Disposition of Subjects*

*Table 4.1*

*Demographic Information for the Five Individuals Who Completed the Study*

Data	Male	Female
Participant	3	2
Average Age	52	50.5
Current Tobacco Use	0	0
Currently Taking Hypertension Medications	2	1
Currently Taking Dyslipidemia Medications	2	1
History of Heart Disease	0	0

#### *Metabolic Components*

The data as it relates to the five metabolic disorders that comprise metabolic syndrome (waist, glucose, blood pressure, HDL, and triglycerides) were only computed

for participants who completed the study (see Table 4.2). Biometric measurements were taken at baseline, day 30, day 90, and day 180 for waist, glucose, systolic blood pressure, and diastolic blood pressure. Biometrics for HDL and triglycerides were taken at baseline, day 90, and day 180. The data was analyzed using SPSS version 16.0. The mean, standard deviation and significance level were obtained for all metabolic syndrome components at baseline and were compared to day 180.

*Table 4.2*

*Descriptive Statistics for Metabolic Syndrome Component at Baseline and Day 180*

Metabolic Syndrome Component	Baseline		Day 180		Significance
	Mean	Standard Deviation	Mean	Standard Deviation	
Waist	120.90	24.79	115.10	22.86	p = 0.007
Glucose	100.80	22.90	98.40	7.30	p = 0.828
SBP	135.80	16.76	120.80	2.20	p = 0.108
DBP	85.60	5.32	71.20	6.38	p = 0.047
HDL	32.80	11.37	34.40	4.57	p = 0.327
Triglycerides	207.60	75.02	216.00	124.42	p = 0.840
Average Number Components Males	3.67	0.58	3.00	1.41	
Average Number Components Females	4.00	1.41	4.00	1.41	

\* 95% Confidence Level and  $\alpha$  0.05

*Waist.* The average decrease in waist size from baseline to day 180 ( $5.8 \text{ cm} \pm 2.6 \text{ cm}$ ) was evaluated using paired t-test. There was a statistically significant change at the 95% confidence interval ( $p = 0.007$ ) (see Figure 4.2).

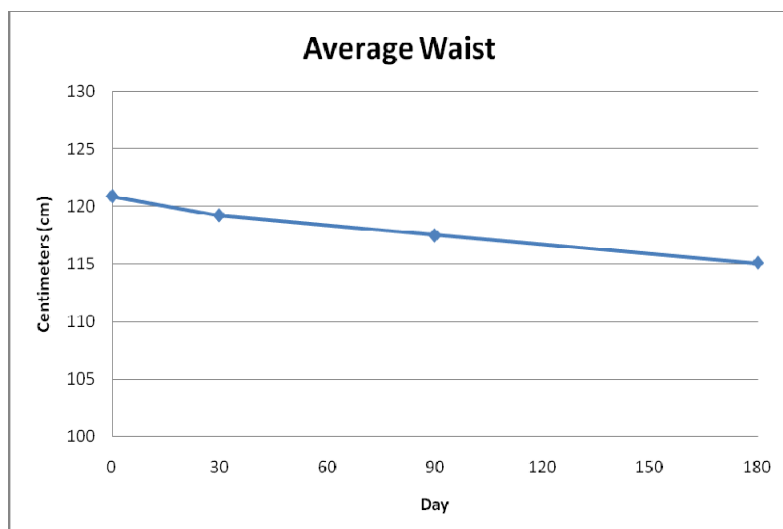


Figure 4.2. Average Waist Size of Participants from Baseline to Day 180

*Glucose.* The average decrease in glucose from baseline to day 180 ( $2.4 \text{ mg/dl} \pm 15.6 \text{ mg/dl}$ ) was evaluated using paired t-test. There was a non-statistically significant change at the 95% confidence interval ( $p = 0.828$ ) (see figure 4.3).

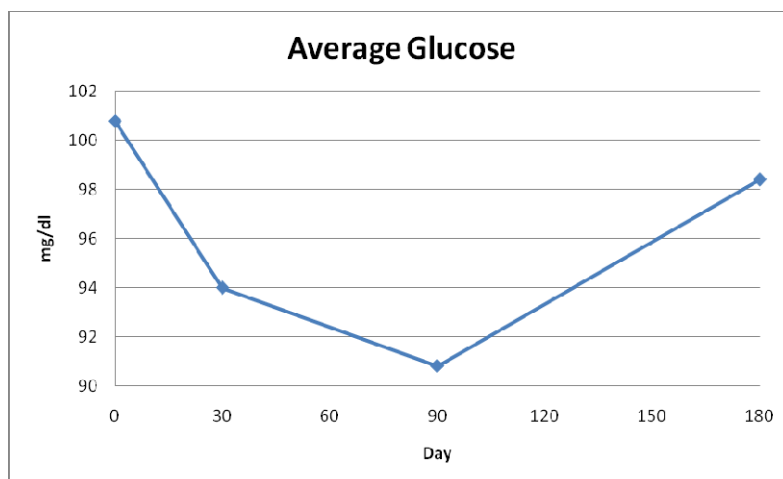
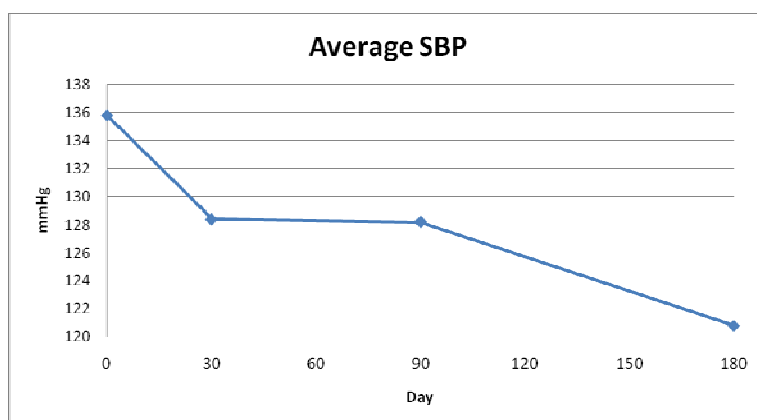


Figure 4.3. Average Glucose of Participants from Baseline to Day 180

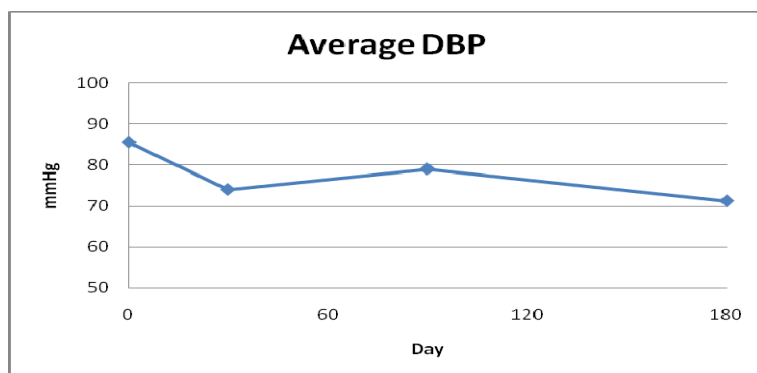
*Systolic Blood Pressure (SBP).* The average decrease in SBP from baseline to day 180 ( $15.0 \text{ mmHg} \pm 11.78 \text{ mmHg}$ ) was evaluated using paired t-test. There was a non-

statistically significant decrease in SBP at the 95% confidence interval ( $p = 0.108$ ) (see figure 4.4).



*Figure 4.4. Average Systolic Blood Pressure of Participants from Baseline to Day 180*

*Diastolic Blood Pressure (DBP)*. The average decrease in DBP from baseline to day 180 ( $14.4 \text{ mmHg} \pm 1.06 \text{ mmHg}$ ) was evaluated using paired t-test. There was a statistically significant decrease in DBP at the 95% confidence interval ( $p = 0.047$ ) (see figure 4.5).



*Figure 4.5. Average Diastolic Blood Pressure of Participants from Baseline to Day 180*

*High Density Lipoprotein (HDL)*. The average increase in HDL from baseline to day 180 ( $1.6 \text{ mg/dl} \pm 1.16 \text{ mg/dl}$ ) was evaluated using paired t-test. There was a non-statistically significant increase of HDL at the 95% confidence interval ( $p = 0.327$ ) (see figure 4.6).

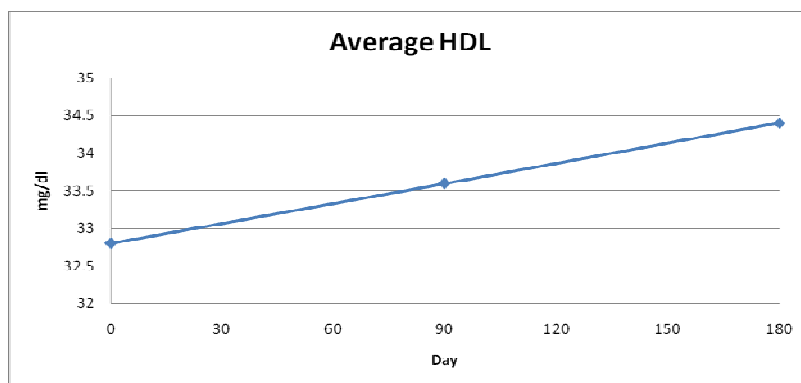


Figure 4.6. Average HDL Levels of Participants from Baseline to Day 180

*Triglycerides.* The average increase in triglycerides from baseline to day 180 ( $8.4 \text{ mg/dl} \pm 49.39 \text{ mg/dl}$ ) was evaluated using paired t-test. There was a non-statistically significant increase of triglycerides at the 95% confidence interval ( $p = 0.084$ ) (see figure 4.7).

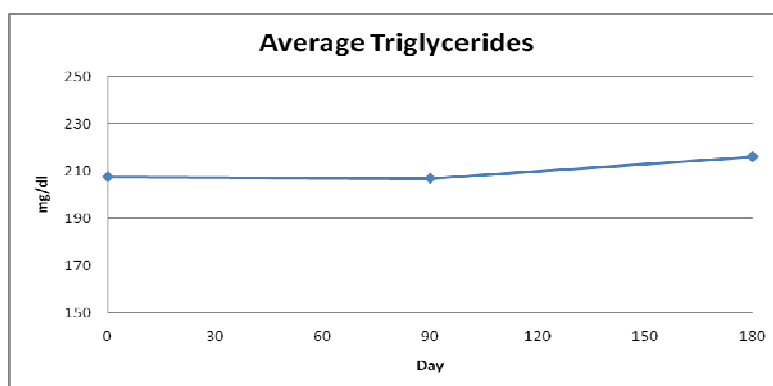


Figure 4.7. Average Triglyceride Levels of Participants from Baseline to Day 180

#### *Exercise and Diet*

*Exercise.* The exercise segment of the intervention was evaluated on a compliant noncompliant basis. As previously stated the participants were encouraged to exercise at least three (ideally five) days per week at a moderate level and to record their exercise time on the exercise log. Exercise was defined as additional time during the day separate

from work or other normal daily activities. Appendix E contains the exercise handout given to participants.

For the purposes of this study participants were judged to have been compliant with the exercise portion of the intervention if their average exercise minutes during a week were greater than or equal to 135 minutes (45 minutes per day for 3 days). Weekly minutes were totaled for the time period and the average for the time period their determined their compliance for that time period (baseline to day 30, day 31 to day 90, day 91 to day 180). The participant was determined to compliant overall if they were compliant for two (2) of the three (3) periods evaluated. Table 4.3 shows the exercise compliance for each participant at day 30, day 90, day 180, and their overall compliance rating. Eighty percent (80%) of the participants were compliant with the exercise portion of the intervention. The compliance average ranged from a high of 337.69 minutes (60 minutes a day for 5.6 days a week) per time period to a low of 144.23 minutes (45 minutes a day for 3.2 days a week) per time period.

*Diet.* The dietary segment of the intervention was also evaluated on a compliant noncompliant basis. The participants were encouraged to modify their current dietary practices to coincide with the recommended servings for specific food groups (see appendix F).

Table 4.3

*Average Minutes Exercised by Participant, Time Period, and Overall Rating*

Participant	Day 30	Day 90	Day 180	Average Minutes	Overall Rating
4	78.75	140.63	67.31	95.56	Noncompliant
6	206.25	226.25	144.62	192.37	Compliant
8	183.75	101.25	147.69	144.23	Compliant
9	315	301.88	293.08	303.32	Compliant
14	333.75	341.25	338.08	337.69	Compliant

To evaluate compliance the recommended daily servings were averaged for each week. If the recommended daily servings for the week was greater than or equal to the recommended servings the participant was judged to be compliant for that food group. If the number of compliant food groups for the week was greater than or equal to the number of noncompliant food groups then the participant was judged to be compliant with the dietary component for that week. If the weeks of compliance for the time period (baseline to day 30, day 31 to day 90, day 91 to day 180) were greater than or equal to the number of weeks of noncompliance then the participant was judged to be compliant for that time period. If the participant was compliant for two of the three time periods they were judged to be compliant with the dietary portion of the intervention. Table 4.4 show the dietary compliance for each participant at day 30, day 90, day 180, and their overall compliance rating.

As can be observed in table 4.4 only one participant (20 percent) was compliant with the dietary portion of the intervention. This low level of compliance makes evaluation of the impact of dietary changes difficult. Table 4.5 demonstrates the average daily serving change for each participant by food groups. This difference was obtained by

comparing the daily average servings by food group for the first four weeks of the study and comparing them to the daily average servings by food group for the last four weeks of the study. This reason for this evaluation is to look for positive changes in eating habits of the 180 days of the study.

Participant 4 had overall the largest average change of dietary practices over the 180 days of the study at 0.4608 servings. He increased his grains, vegetables, and nuts/seeds/legumes/beans by more than 1.5 servings a day and decreased his sweets and red meat.

*Table 4.4*

*Dietary Compliance by Participant, Time Period, and Overall Rating*

Participant	Day 30	Day 90	Day 180	Overall Rating
4	Compliant	Compliant	Compliant	Compliant
6	Noncompliant	Noncompliant	Noncompliant	Noncompliant
8	Noncompliant	Noncompliant	Noncompliant	Noncompliant
9	Noncompliant	Noncompliant	Noncompliant	Noncompliant
14	Noncompliant	Noncompliant	Noncompliant	Noncompliant



Table 4.5

*Average Daily Serving Change for Each Participant by Food Group*

Food Group	Participant 4 Daily Average Change	Participant 6 Daily Average Change	Participant 8 Daily Average Change	Participant 9 Daily Average Change	Participant 14 Daily Average Change
Grains	1.56	1.05	-0.10	2.58	0.19
Vegetables	1.50	0.94	0.48	-0.08	-1.58
Nuts/Seed/Legumes/ Beans	2.33	0.27	-0.20	-0.32	0.04
Fruit	0.36	-0.71	-0.04	-0.96	0.54
Olive Oil	0.32	-0.25	-0.07	0.93	0.14
Cheese & Yogurt	-0.19	-0.72	-0.28	0.58	0.53
Red Wine	-0.07	0.00	1.00	0.30	0.54
Fish	-0.28	-0.25	0.04	-2.46	0.14
Poultry	0.16	0.35	-0.44	-1.79	-0.83
Eggs	0.00	0.00	-0.13	-0.04	0.17
Sweets	-0.08	2.50	0.53	-0.79	-0.18
Red Meat	-0.08	0.61	0.24	-0.05	0.06
Average Change	0.4608	0.3158	0.0858	-0.175	-0.02

\* Negative number indicates decrease in number of average daily servings.

This chapter is a review of the subjects and the results of the dietary and exercise interventions on the various metabolic components. The compliance of the subjects with the exercise and dietary interventions was also reviewed as well as the average overall changes in serving changes for the selected food groups from the first week of the study to the last week of the study.

## Chapter Five: Discussion

This chapter provides a discussion of the project outcomes and issues that developed during the completion of the project. This is followed by a discussion of the limitations of the study as well as recommendations for future projects of this subject and for future research.

### *Discussion*

The purpose of this project was to identify the effects of an intensive dietary and exercise program on patients with metabolic syndrome. Specifically, the project was to examine the effects of the program on waist circumference, blood pressure, HDL cholesterol, triglycerides, and fasting glucose. By extension the desired outcome was to move patients from a prothrombotic metabolic syndrome state to a less prothrombotic non-metabolic syndrome state. None of the five participants who completed the study moved to the non-metabolic state. All but one participant were compliant with the exercise portion. Interestingly, this person was the only one who was compliant with the dietary portion of the intervention.

The evidence suggests that diet and exercise programs are effective in controlling the components of metabolic syndrome. But, as with this study, the complexity of dietary and exercise interventions are complex impede adherence, both in execution and evaluation. These types of interventions require significant lifestyle changes and if they are to be successful the participants must exhibit concerted long term effort.

### *Limitations and Challenges*

There were multiple challenges in this project. These include issues related to the sample, the metabolic components, adherence to the intervention, and even the selection of participants.

*Sample.* The final sample size was five participants (three male and two female). This small sample size at the completion of the study precludes dynamic statistical evaluation. Future projects of this type should begin with a more robust initial sample size. If possible a beginning sample size of at least 100 participants would be more appropriate. With an expected attrition of approximately 50% there would be a more realistic approximation of a normal distribution.

This increased number of participants would increase the complexity of the logistics and record keeping. Multiple meeting days and times may be necessary to accommodate the participants and their individual needs. A meeting area large enough to accommodate the maximum number of participants would be required and since the biometrics are taken in a fasting state a greater amount of appropriate foods would be required for participant consumption at each meeting. Increasing the number of participants would also increase the cost of the study and funding would need to be addressed at an early stage. A specific data entry individual would be required if there were an increased number of participants. The primary investigator would have a difficult time performing as data entry, coordinator, and exercise counselor. It would also be desirable to have input from a statistician at a very early stage to assist with set up of Excel and SPSS type programs prior to beginning of data collection.

*Metabolic components.* The small sample size (n=5) did not lend itself to strong statistical evidence of change in the metabolic components. However, the small sample size did not preclude the outcome of a statistically significant decrease in waist size. Although not statistically significant, systolic blood pressure and high density lipoprotein (HDL) trended in the desired direction (down for SBP and up for HDL). An increase in the number of participants or a lengthening of the study period (preferably both) may have produced more dynamic changes in these metabolic components. In contrast, the glucose and triglycerides averages were trending upward. Again the sample size was too small to hypothesize with any degree of certainty the possible explanation.

The overall compliance with the exercise regimen may account for some of the improvement in waist size, blood pressure, and HDLs. The literature from Carroll and Dudfield (2004) and my own anecdotal clinical experience, indicates that waist size, blood pressure, and HDL are affected more by exercise rather than diet, while glucose and triglycerides seem to be less affected by exercise. This is an important aspect for future research.

*Diet and exercise.* The exercise portion of the intervention was the easier of the two to track and had a significantly higher adherence rate when compared to diet. One possible explanation is that exercise is a finite time commitment during the day while dietary changes are necessary throughout the day and are therefore more difficult to maintain and track. Another difference that adds to the complexity of diet as compared to exercise is that there are 12 components to the dietary intervention and one component to the exercise component. An addition to the data collection should have been to establish

pre-study levels of exercise and compare them to post-study levels of exercise. This could have shown if there was a change in life style with reference to exercise.

As would be expected the dietary portion of the intervention was more complicated and time consuming for the participants. This is inherent in any dietary intervention that is designed to significantly change dietary lifestyle. Another difficulty with the dietary portion was overcoming the cultural differences in the diet. The Mediterranean style of eating is vastly different from the typical southeastern United States diet. This difference could have been blunted by limiting the number of food groups evaluated. The dietary portion also presented several barriers to change that had not been addressed in the initial planning of the study. The participants did not accept the need for the changes in their diet, they preferred their current diets because of tradition, and many were set in their ways and did not truly wish to make dramatic changes in their habits.

*Record keeping and meetings.* Self reporting has inherent problems one of which is the constant possibility of inaccurate information being submitted. It is difficult to judge the accuracy of entries in self reporting type data. Some reasons for this possible inaccuracy include the participant wanting to appear to be compliant in order to be praised by the researchers. They may also know and or like the researcher, they might feel that a greater appearance of compliance may help the researcher. These biases would be difficult if not impossible to overcome without making the collection process much more complicated. If the collection process were more complicated the researchers would run the risk of decreasing participation.

Meeting at 90 and 180 days decreased the number of data points and made it difficult to note small incremental changes. Monthly meetings would have had several positive impacts. This increased frequency of meetings would have made it possible to intervene with counseling earlier and would have reinforced good changes and allowed for changing non helpful changes prior to them being made permanent. Monthly meetings would also have allowed for identifying individual barriers to diet and exercise as well as the opportunity to overcome the barriers. Having monthly meetings would have increased the number of data points, but would have also increased the scheduling problems for participants which could have increased the dropout rate. As previously mentioned an increase in the number of meetings would also have increased the monetary cost of the project.

*Selection of participants.* It is difficult to gage the success of the interventions if the participant is currently taking medications for hypertension or dyslipidemia. It may be construed as unethical to expose participants to the increased risk of end organ damage and adverse events by stopping their existing medications. Ideally the target population for this type of intervention would be individuals who meet the diagnostic criteria for metabolic syndrome, but have not been placed on medication. This early intervention is possible by selectively targeting individuals with metabolic syndrome who are medication naive.

#### *Implications for Future Research*

Future research at the practice level should target dietary changes of five food groups rather than the 12 in this study. The food groups to target would be increase olive oil, fish/chicken, and whole grains, as well as decrease concentrated sweets and red

meats. This less intensive intervention would allow the participants to make less extreme dietary changes and would be less of a challenge to the southern culture of food choices. Since the changes would be less extreme the complexity of participant record keeping would be decreased and could thereby increase adherence.

Future research at the practice level targeting exercise changes should differentiate the changes that take place with different types of moderate exercise as well as between age groups, and genders. This would allow more precise targeting of exercise interventions by types of exercises, age group, and gender.

#### *Implications for Practice*

The research undertaken for this project has clarified dietary and exercise advice given to patient with metabolic syndrome. The dietary suggestions to increase olive oil, fish/chicken, and whole grains and decrease concentrated sweets and red have been incorporated into the standards of care at my practice setting. Dietary and exercise interventions have been incorporated into suggested lifestyle changes for pre-metabolic syndrome patients as well as metabolic syndrome patients.

If these dietary and exercise changes can be implemented prior to an actual diagnosis of metabolic syndrome it would, in all likely hood, decrease the incidence of metabolic syndrome and thereby decrease the prevalence of heart disease and diabetes.

#### *Conclusion*

Metabolic syndrome continues to be a serious health problem in the United States. The presence of metabolic syndrome significantly increases the risk of developing type II diabetes and cardiovascular disease by producing a prothrombic state. The independent risk factors that create this prothrombic state increases the risk of micro and macro

vascular changes and eventually to end organ damage. Dietary and exercise lifestyle changes are effective at changing this prothrombotic state. The challenge is motivating the individuals to make the necessary lifestyle changes prior to end organ damage.

This study even with a small sample size showed that waist size, systolic blood pressure, diastolic blood pressure, and high density lipoprotein levels were trending towards levels that would remove the patient from the diagnosis of metabolic syndrome. The largest benefit for the general population would result from intervention prior to a diagnosis of hypertension and diabetes. This would help decrease the cost of medical treatment and hospitalization.

If early intervention would decrease only systolic blood pressure by 12 – 13 mmHg over 4 years a corresponding decrease of 21% in coronary heart disease, a decrease of 37% in stroke, and a decrease of 25% in cardiovascular deaths could be expected (USDHHS, 2005). This decrease in coronary heart disease, stroke, and cardiovascular death would translate in to billions of dollars save in health care expenditures.



## Appendix A. Review of the Evidence

Author (Dates)	Type	N	Comments
Meta-analysis and systematic reviews			
Gami et al. (2007)	Meta-analysis and systematic review of longitudinal studies of metabolic syndrome and incidence of cardiovascular events and death.	36 studies, 172,573 subjects	Purpose was to assess the association between metabolic syndrome and cardiovascular events and death by reviewing longitudinal studies. Evidence suggested metabolic syndrome increased the risk of cardiovascular events and death.
Mellen et al. (2006)-	Meta-analysis of the effects of whole grain intake on cardiovascular disease	7 studies, 285,376 subjects	Epidemiological cohort studies showing an inverse relationship between whole grain intake and CVD. 2.5 servings daily associated with a 21% decrease in risk of CVD. 229 post menopausal women study showed 6 or more servings per week was associated with a 40% decrease in coronary atherosclerotic progression.
Serra-Majem et al. (2006)	Systematic review of outcomes of the use of the Mediterranean diet	43 clinical trials, 17031 subjects	13 countries represented, conclusion that scientific evidence for Mediterranean Diet was observational and personal reviews. 24 of the 43 studies included less than 60 subjects. Authors found that Mediterranean diet recommendations needed to be evidenced based and observational epidemiological studies were needed in the Mediterranean countries.
Dansinger et al. (2007)	Meta-analysis on effect of dietary counseling for weight loss	40 studies with 63 treatment groups, 26 with diet and 27 with diet and exercise	RCTs comparing dietary counseling-based weight loss against usual care produced a mean net treatment effect of approximately 6% (5kg) of weight loss at 1 year. Modest weight loss reduces cardiovascular risk factors hyperglycemia, hypertension, & hypercholesterolemia. Modest weight loss through dietary and lifestyle counseling reduces risk of development of diabetes in glucose-intolerant individuals.
Franz et al. (2007)	Systematic review & meta-analysis of weight-loss clinical trials with a minimum of 1 year of follow-up	80 studies included with 26,455 subjects enrolled and randomized and a overall attrition rated of 31%	All studies with a minimum of 1 year of follow-up, dependent variable weight-loss in treatment verses control arm. Treatments included exercise alone, diet alone, diet & exercise, meal replacements, very-low-energy diet, orlistat, sibutramine, and advice alone. Interventions of diet alone, diet and exercise, and meal replacement decreased weight by 5 – 9% at 6 months, then plateau with a 4.8 – 8% stabilization at 12

Author (Dates)	Type	N	Comments
			months and 3 – 4.3% reduction out to 48 months. Weight loss and maintenance for diet medications is similar to diet plus exercise at 6 months, but a mean weight loss of 2 – 5% above exercise intervention is noted at 24 months. Very-low-energy diets resulted in dramatic weight loss followed by rapid and substantial weight gain. Exercise alone or advice did not result in successful weight loss, but no weight gain was noted.
Reviews			
Carroll & Dudfield (2004)	Review of the relationship between exercise, diet and metabolic syndrome.	20 male prevalence studies, 93111 subjects; 15 female prevalence studies, 64973 subjects; 6 cross-sectional & 1 prospective studies, 22521 subjects; 3 IGT RCTs studies, 4333 subjects; 15 exercise RCTs, 1017 subjects;	Epidemiology reviewed, prevalence of metabolic syndrome clustered by age groups reviewed, reviewed exercise recommendations, dietary recommendations, positive effects of exercise and dietary changes. Authors did not review inclusion criteria for articles. Validity of studies was not discussed. Possible relevant articles may have been overlooked although Table XI did give characteristics of methodology of RCTs evaluated. 30 to 60 min exercise 3 – 5 times a week at 40 – 60% VO2 max shows positive outcome with reducing metabolic syndrome.
Giugliano & Esposito, (2008)	Review of Studies	N/A	Review of studies involving Mediterranean diet and obesity, cardiometabolic risk, diabetes, metabolic syndrome as well as the possible protective mechanism of Mediterranean diet.
Johnson & Weinstock (2006)	Review for Clinicians	N/A	Review of the three diagnostic criteria for metabolic syndrome, review of controversies around the differences in the diagnostic criteria. Metabolic syndrome is an indicator of long-term cardiovascular risk and Framingham is superior for short term risk assessment for cardiovascular risk. ADA and EASD question the clinical value of metabolic syndrome. Discusses flaws with ATP III criteria.
Kaplan, & Keil,	Review Literature	N/A	Review of literature with reference to CVD risk factors and socioeconomic status and the factors related to socioeconomic status.

Author (Dates)	Type	N	Comments
(1993)			Discusses measurement of socioeconomic status/social class most common being education level, income, occupation, employment status, indexes of social class, measures of living conditions, are-based measures, life span measures, measures of income inequality. Reviews all cause mortality and CV mortality by SES. Risk factors of CV disease discussed and compared by SES. Questions if SES is an independent risk factor for CV disease.
Larion, Denis (2007)	Review of Studies; Primary & Secondary Prevention,	Primary Prevention 4 studies N=1123, Secondary Prevention 2 studies N=11928	The Mediterranean-type diet lowered BMI, total, LDL- and triglyceride, insulinemia, and glycemia. Mediterranean-style diet promoted beneficial changes for fasting glucose, systolic blood pressure, the cholesterol/HDL cholesterol ratio. Mediterranean style diet was compared with low fat low cholesterol diet and Mediterranean proved more beneficial.
<b>Guidelines</b>			
Armstrong, (2006)	Practice Guidelines	N/A	Primary goal to reduce risk for CVD, first line therapy related to major risk factors (elevated LDL, HTN, DM), Metabolic syndrome rarely manifests in the absence of obesity and physical inactivity. Clinical management goals reviewed for abdominal obesity, physical activity, diet, dyslipidemia, elevated blood pressure, prothrombic and proinflammatory states, and elevated fasting glucose
U.S. Department of Health and Human Services (2003)	Clinical Guidelines JNC-7	N/A	Guidelines for management of HTN. The ultimate goal of therapy is to reduce cardiovascular & renal morbidity & mortality. A healthy lifestyle by all persons is critical for the prevention of HTN & is essential part of the management of those with HTN. Major lifestyle modifications are shown to lower BP (weight reduction in overweight or obese, adoption of the Dietary Approaches to Stop Hypertension (DASH) eating plan which is rich in potassium and calcium, dietary sodium reduction, physical activity, & moderation of alcohol consumption.
American Diabetes	Clinical Guidelines Standards of medical care in	N/A	National guidelines for diagnosis and management of diabetes. Hperglycemia insufficient to be diagnosed as diabetes is referred to as

Author (Dates)	Type	N	Comments
Association (2007)	diabetes.		as either IFG or impaired glucose tolerance (IGT), depending on whether it is identified through an FPG or an OGTT: • IFG FPG 100 mg/dl (5.6 mmol/l) to 125 mg/dl (6.9 mmol/l), • IGT 2-h plasma glucose 140 mg/dl (7.8 mmol/l) to 199 mg/dl (11.0 mmol/l) Recently, IFG and IGT have been officially termed pre-diabetes. Both categories, IFG and IGT, are risk factors for future diabetes and cardiovascular disease.
National Institutes of Health, ATP III, (2001)	Clinical Guidelines	N/A	ATP III guidelines for lowering cholesterol and establishing criteria for metabolic syndrome. Therapeutic life style changes recommended. Dietary recommendations included.
<b>Studies</b>			
Simons, et al., (2007)	Longitudinal cohort study	2085	60 years old or older followed for 16 years; Duppo New South Wales; main outcome measures CHD events, ischemic stroke, total mortality. Results metabolic syndrome increased risk in older individuals for CHD events, stroke events, and total mortality greater than general population of same age.
Lorenzo, et al., (2007)	Longitudinal cohort study	2646	Ages 25 - 64 with 7.4 years of follow-up; conclusion metabolic syndrome is associated with a significant increase risk of CVD especially in men older than 45 & women older than 55. Metabolic syndrome increases CVD risk in people who are free of CVD or DM. CVD risk prediction by metabolic syndrome is inferior compared to Framingham. Compared ATP III, IDF, and WHO definitions all have a similar ability to predict CVD & diabetes, but they have differing sensitivity and false positive rate.
Loucks, et al., (2006)	Cross-sectional study	11107	Used NCEP-R diagnosis criteria; SEP measured by education or income is associated with metabolic syndrome in women (white, black, and Mexican-American), black women education 12 years, but not <12 years was linked to metabolic syndrome; mechanisms that link SEP to

Author (Dates)	Type	N	Comments
			metabolic syndrome health behaviors, psychological stress, & access to health care.
Santos, et al. (2008)	Cross-sectional cohort study	1962	Location Portugal, gender influenced the association of socio-economic status with metabolic syndrome. Lower socio-economic class defined by education and occupation. Females in lower classes increased prevalence men no association noted.
Guize, et al. (2007)	Longitudinal cohort study	60754	French study; men aged 52.6 +/- 8.3, women aged 54.7 +/-; mean follow-up 3.57 years +/- 1.12; prevalence of metabolic syndrome adjusted for age, sex, classical risk factors, socioprofessional standing; used ATP III, NCEP-R, and IDF definitions; three and four component combinations that showed increased risk of all cause mortality.
Belahsen & Rguibi (2006)	Population	N/A	Study discussing trends in southern Mediterranean countries with reference to diet and activity levels. Away from traditional Med diet towards western diet and the increasing incidence of obesity in the area.
Expert Opinion			
Stone, & Schmeltz, (2007)	Expert Opinion	N/A	Reviewed epidemic of metabolic syndrome and obesity, clinical impact, (CVD, DM II, inflammation & prothrombotic state), treatments (lifestyle modification, pharmacology, surgery) & expert opinion on how to treat metabolic syndrome – treat each of its individual components, pharmacologic therapy crucial, but relying solely on medications may be counter productive, focus on root causes and start with therapeutic lifestyle changes (diet, exercise).

Appendix B Patient Profile

# PATIENT PROFILE

Patient:	
Date of birth:	Sex:
Occupation:	
Primary Physician:	

Allergies and Reactions	Date of Entry

Date	Onset	Permanent Problem

Date	Onset	Permanent Problem

Significant Illness	Dates			
A				
B				
C				
D				
E				
F				

Dates	Previous Surgery
	Appendectomy
	Cholecystectomy
	Hysterectomy
	Tonsils/ Adenoids

Significant Family History	M	F	Sib
CAD			
Colon Ca			
Breast Ca			
HTN			
Diabetes Mellitus			
CVA (Stroke)			
Prostate/Other Ca			
Renal Disease			
Sickle Cell			

Significant Social History			
Married	Single	Divorced	Widowed
Prior Occupational Exposure			
Transfusions			
Coffee			
Drug Usage			
Alcohol			
Smokes	Current	X	previous years

## Appendix C Data Collection Form

\_\_Participant Number

Variable	Data			
	Baseline	30 Days	90 Days	180 Days
Date				
Age (years)				
Gender				
Smoking status (packs per day)				
Height (inches)				
Weight (pounds)				
Waist circumference (cm)				
Glucose (mmol/l)				
Systolic blood pressure (mmHg)				
Diastolic blood pressure (mmHg)				
Triglycerides (mmol/l)				
High-density lipoprotein (mmol/l)				
Low-density lipoprotein (mmol/l)				

## Appendix D Exercise Handout

**Exercise****1. What is physical activity?**

Physical activity simply means movement of the body that uses energy. Walking, gardening, briskly pushing a baby stroller, climbing the stairs, playing soccer, or dancing the night away are all good examples of being active.

- Moderate physical activities include:
  - Walking briskly (about 3 ½ miles per hour)
  - Hiking
  - Gardening/yard work
  - Dancing
  - Golf (walking and carrying clubs)
  - Bicycling (less than 10 miles per hour)
  - Weight training (general light workout)
  
- Vigorous physical activities include:
  - Running/jogging (5 miles per hour)
  - Bicycling (more than 10 miles per hour)
  - Swimming (freestyle laps)
  - Aerobics
  - Walking very fast (4 ½ miles per hour)
  - Heavy yard work, such as chopping wood
  - Weight lifting (vigorous effort)
  - Basketball (competitive)

Some physical activities are not intense enough to help you meet the recommendations. Although you are moving, these activities do not increase your heart rate, so you should not count these towards the 45 or more minutes a day that you should strive for. These include walking at a casual pace, such as while grocery shopping, and doing light household chores.



## 2. Why is physical activity important?

Being physically active is a key element in living a longer, healthier, happier life. It can help relieve stress and can provide an overall feeling of well-being. Physical activity can also help you achieve and maintain a healthy weight and lower risk for chronic disease. The benefits of physical activity may include:

- Improves self-esteem and feelings of well-being
- Increases fitness level
- Helps build and maintain bones, muscles, and joints
- Builds endurance and muscle strength
- Enhances flexibility and posture
- Helps manage weight
- Lowers risk of heart disease, colon cancer, and type 2 diabetes
- Helps control blood pressure
- Reduces feelings of depression and anxiety

Physical activity and nutrition work together for better health. Being active increases the amount of calories burned. As people age their metabolism slows, so maintaining energy balance requires moving more and eating less.

Some types of physical activity are especially beneficial:

- *Aerobic activities* – speeds heart rate and breathing and improves heart and lung fitness. Examples are brisk walking, jogging, and swimming.
- *Resistance, strength building, and weight-bearing activities* – helps build and maintain bones and muscles by working them against gravity. Examples are carrying a child, lifting weights, and walking. They help to build and maintain muscles and bones.
- *Balance and stretching activities* – enhances physical stability and flexibility, which reduces risk of injuries. Examples are gentle stretching, dancing, yoga, martial arts, and t'ai chi.

## 3. How much physical activity is needed?

- At a minimum, do *moderate* intensity activity for 45 minutes. Try to exercise at least 5 days a week, but preferably every day. This is in addition to your usual daily activities. Increasing the intensity or the amount of time of activity can have additional health benefits and may be needed to control body weight.
- About 60 minutes a day of moderate physical activity may be needed to prevent weight gain. For those who have lost weight, at least 60 to 90 minutes a day may be needed to maintain the weight loss. At the same time, calorie needs should not be exceeded.
- While 30 minutes a day of moderate intensity physical activities provide health benefits, being active for longer or doing more vigorous activities can provide even greater health benefits. They also use up more calories per hour. No matter what activity you choose, it can be done all at once, or divided into two



or three parts during the day. When dividing exercise during the day 10-minute bouts of activity count toward your 45 minute total.

#### 4. Calories used:

A 154-pound man (5' 10") will use up about the number of calories listed doing each activity below. **Those who weigh more will use more calories, and those who weigh less will use fewer.** The calorie values listed include both calories used by the activity and the calories used for normal body functioning.

Moderate physical activities:	Approximate calories used by a 154 pound man	
	In 1 hour	In 30 minutes
Hiking	370	185
Light gardening/yard work	330	165
Dancing	330	165
Golf (walking and carrying clubs)	330	165
Bicycling (less than 10 miles per hour)	290	145
Walking (3 ½ miles per hour)	280	140
Weight training (general light workout)	220	110
Stretching	180	90
Vigorous physical activities:	In 1 hour	In 30 minutes
Running/jogging (5 miles per hour)	590	295
Bicycling (more than 10 miles per hour)	590	295
Swimming (slow freestyle laps)	510	255
Aerobics	480	240
Walking (4 ½ miles per hour)	460	230
Heavy yard work (chopping wood)	440	220
Weight lifting (vigorous effort)	440	220
Basketball (vigorous)	440	220

#### 5. Tips for increasing physical activity.

- Make physical activity a regular part of the day.** Choose activities that you enjoy and can do regularly. Fitting activity into a daily routine can be easy—such as taking a brisk 10 minute walk to and from the parking lot or bus stop. Join an exercise class. Keep it interesting by trying something different on alternate days. What's important is to be active most days of the week and make it part of daily routine. For example, to reach a 30-minute goal for the day, walk the dog for 10 minutes before and after work, and add a 10 minute walk at lunchtime. Swim 3 times a week and take a yoga class on the other days. Make sure to do at least 10 minutes of the activity at a time, shorter



bursts of activity will not have the same health benefits. To be ready anytime, keep some comfortable clothes and a pair of walking or running shoes in the car and at the office.

- **At home:** Join a walking or at the local shopping support and baby in a stroller. Get the enjoy an afternoon bike up and down the soccer or while watching the kids just watch the dog walk. the car. Walk, skate, or Do stretches, exercises, or pedal a stationary bike while watching television. Mow the lawn with a push mower. Plant and care for a vegetable or flower garden Play with the kids—tumble in the leaves, build a snowman, splash in a puddle, or dance to favorite music.



group in the neighborhood mall. Recruit a partner for encouragement. Push the whole family involved—ride with your kids. Walk softball field sidelines play. Walk the dog—don't Clean the house or wash cycle more, and drive less.

- **At work:** Get off the bus or subway one stop early and walk or skate the rest of the way. Replace a coffee break with a brisk 10-minute walk. Ask a friend to go with you. Take part in an exercise program at work or a nearby gym. Join the office softball or bowling team. Use the stairs not the elevator. Do not use the closest rest room to your office.



- **At play:** Walk, jog, skate, or cycle. Swim or do water aerobics. Take a class in martial arts, dance, or yoga. Golf (pull cart or carry clubs). Canoe, row, or kayak. Play racket ball, tennis, or squash. Ski cross-country or downhill. Play basketball, softball, or soccer. Hand cycle or play wheelchair sports. Take a nature walk. Most important – have fun while being active!



This handout was adapted from information obtained from [http://www.mypyramid.gov/pyramid/physical\\_activity.html](http://www.mypyramid.gov/pyramid/physical_activity.html)

## Appendix E Recommended Servings of Food Groups

<u>Food Group</u>	<u>Recommended Servings per Week</u>	<u>Serving Size</u>
Sweets	Maximum of 7	1 teaspoon
Red Meat	Maximum of 4	3 ounces
Grains	Minimum of 42	1 slice of bread, ½ bagel, 1 cup cereal, ½ cup pasta or rice
Eggs	Maximum of 3	1 egg
Poultry	Minimum of 3	3 ounces
Fish	Minimum of 3	3 ounces
Wine	Minimum of 7	3 – 4 ounces
Olive oil	Minimum of 4	1 tablespoon
Fruits	Minimum of 21	1 cup fresh, ½ cup canned, ½ cup dried
Beans, legumes, nuts	Minimum of 14	Nuts/Seeds 1 ounce, Beans/Legumes ½ cup
Vegetables	Minimum of 21	1 cup raw, ½ cup cooked
Cheese & yogurt	Minimum of 14	Cheese 1 ounce, Yogurt 1 cup

## References

- Belahsen, R., & Rguibi, M. (2006). Population health and Mediterranean diet in southern Mediterranean countries. *Public Health Nutrition*, *9*, 1130-1135.
- Carroll, S., & Dudfield, M. (2004). What is the relationship between exercise and metabolic abnormalities? *Sports Medicine*, *34*, 371-418.
- Gami, A. S., Witt, B. J., Howard, D. E., Erwin, P. J., Gami L. A., Somers, V. K., et al. (2007). Metabolic syndrome and risk of incident cardiovascular events and death: A systematic review and meta-analysis of longitudinal studies. *Journal of the American College of Cardiology*, *49*, 403-414.
- Giugliano, D., & Esposito, K. (2008). Mediterranean diet and metabolic diseases. *Current Opinion in Lipidology*, *19*, 63-68.
- Guize, L., Thomas, F., Pannier, B., Bean, K., Jego, B., & Bentos, A. (2007). All cause-mortality associated with specific combinations of the metabolic syndrome according to recent definitions. *Diabetes Care*, *30*, 2381-2387.
- Kaplan, G. A., & Keil, J. E. (1993). Socioeconomic factors and cardiovascular disease: A review of the literature. *Circulation*, *88*, 1973-1998.
- Johnson, L. W., & Weinstock, R. S. (2006). The metabolic syndrome: Concepts and controversy. *Mayo Clinical Proceedings*, *81*, 1615-1620.
- Lorenzo, C., Williams, K., Hunt, K. J., & Hafner, S. M. (2007). The National Cholesterol Education Program-Adult Treatment Panel III, International Diabetes Federation, and World Health Organization definitions of the metabolic syndrome as predictors of incident cardiovascular disease and diabetes. *Diabetes Care*, *30*, 8-13.
- Loucks, E. B., Rehkopf, D. H., Thurston, R. C., & Kawachi, I. (2007). Socioeconomic disparities in metabolic syndrome differ by gender: Evidence from NHANES III. *Annals of Epidemiology*, *17*, 19-26.
- Santos, A.C., Ebrahim, S., & Barros, H. (2008). Gender, socio-econominc status and metabolic syndrome in middle-aged and old adults. *BMC Public Health*, *8*, 62.
- Serra-Majem, L., Roman, B., & Estruch, R. (2006). Scientific evidence of interventions using the Mediterranean diet: A systematic review. *Nutrition Reviews*, *64* (2, Part 2), S27-S47.

- Simons, L. A., Simons, J., Friedlander, Y., & McCallum, J. (2007). Does a diagnosis of the metabolic syndrome provide additional prediction of cardiovascular disease and total mortality in the elderly? The Dubbo Study. *Medical Journal of Australia*, 186, 400-403.
- Stone, N. J. & Schmeltz, L. R. (2007). Metabolic syndrome management. *Expert Opinion Pharmacother*, 8, 2059-2075.
- U.S. Department of Health and Human Services. (2005). Preventing Chronic Diseases: Investing Wisely in Health Preventing Heart Disease and Stroke. Retrieved April 25, 2007, from <http://www.cdc.gov/nccdphp/publications/factsheets/Prevention/pdf/cvh.pdf>
- U.S. Department of Health and Human Services. (2003). The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7 Express). Retrieved August 21, 2006, from <http://www.nhlbi.nih.gov/guidelines/hypertension/>

## Vita

Ricky M. Kirby was born in \_\_\_\_\_ in \_\_\_\_\_. He graduated \_\_\_\_\_ high school and was married to his high school sweetheart in 1972 and immediately joined the United States Army. He spent 21 years in the Army in the Combat Engineers and Ordnance Corps.

Upon retiring in 1993 he attended Florida Community College Jacksonville and in 1995 he was awarded an Associate in Arts with Honors and an Associate in Science in Nursing with Honors. After graduation he began his nursing career as a staff nurse at St. Vincent's Medical Center. While a staff nurse at St. Vincent's he was also a clinical instructor for Florida Community College Jacksonville for the Associate of Science in Nursing program and completed his Bachelor of Science in Nursing at the University of North Florida graduating Magna Cum Laude on December 12, 1997. He was accepted into the first Masters of Science in Nursing, Family Nurse Practitioner program at the University of North Florida and graduated on May 4, 2001.

After graduation he accepted a position as a Nurse Practitioner with Diagnostic Cardiology Associates with a primary practice location of St. Vincent's Medical Center. During his employment with Diagnostic Cardiology Associates he performed the duties of an Acute Care Nurse Practitioner. In March of 2003 he accepted a position with Lopez Internal Medicine Associates where he is currently employed. He began the Doctor of Nursing Practice in August 2007 and graduated on December 11, 2009.