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## The Impact of a Mediterranean Diet and Exercise Protocol for Patients with Metabolic Syndrome in a Safety-Net Clinic

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### Abstract

**Background:** Metabolic syndrome is a major health hazard for the entire modern world. Metabolic syndrome is a preventable and treatable condition, whose diagnostic criteria, obesity, insulin resistance, hypertension, and hyperlipidemia, is rapidly becoming a major risk factor for all cause morbidity and mortality. The combined intervention of a Mediterranean diet and exercise protocol has demonstrated substantial improvement in metabolic risk factors.

**Objective/Aims:** This project aimed to evaluate the effectiveness of a Mediterranean diet and exercise protocol on waist circumference, blood pressure, lipid levels, fasting glucose and glycated hemoglobin level, and physical activity and eating behaviors in patients with Metabolic Syndrome in a safety-net clinic. The goals for this project were to restore metabolic abnormalities to healthier or normal parameters by improving healthy lifestyle behaviors.

Additionally, this project aimed to initiate a sustainable protocol at the facility for addressing Metabolic Syndrome. The Mediterranean diet and exercise protocol was implemented over a three-month period.

**Pre- and post-intervention data were collected:** MEDAS and IPAQ scores to measure adherence to Mediterranean diet and exercise, and markers of metabolic function: waist circumference, blood pressure, lipid panel, fasting glucose, and glycated hemoglobin. Follow up phone calls were made to participants one-month after protocol initiation.

**Results:** A paired samples t-test was conducted to determine whether markers of metabolic function differed pre- and post-intervention. The pre- and post- test scores on the MEDAS and IPAQ were analyzed using McNemar's test. The frequency and percentage of compliance with a Mediterranean diet and physical active increased post intervention. McNemar's test determined the increase in compliance with the Mediterranean diet was statistically significant ( $p = 0.034$ ), although the increase in compliance with exercise was not statistically significant. ( $p = 0.094$ ). All markers of metabolic function, except diastolic blood pressure, improved. The improvement in waist circumference ( $p = 0.0051$ ) was the only statistically significant metabolic marker variable.

**Conclusions:** The project intervention, a Mediterranean diet and exercise protocol, revealed a statistically significant improvement in waist circumference and compliance with the Mediterranean diet based on MEDAS questionnaires and exercise levels. All metabolic markers improved, except for diastolic blood pressure. Although improvements were not statistically significant, metabolic function and exercise levels improved over a short intervention time of three months.

**Keywords:** Blood pressure; Exercise; Fasting glucose; Lipid panel; MEDAS scores; Mediterranean diet; Metabolic syndrome

### Background and Significance to Healthcare

Metabolic Syndrome is a complex condition with potentially deadly consequences. Although Metabolic Syndrome has been observed in all ages, genders, races, and socioeconomic levels, vulnerable populations are disturbed disproportionately by metabolic abnormalities [1]. Metabolic Syndrome is associated with diabetes and cardiovascular morbidity and mortality [2]. A cardiovascular health study reported patients with MetS had higher 10- year medical costs of about 50% compared to those without the syndrome [3].

Individuals with MetS have 38% more coronary and cerebrovascular events. This equates to more inpatient stays and frequent primary care visits. Coupled with an increase of MetS in advancing age, the long-term costs will continue to grow and negatively affect the health and economy across the globe [3].

Early detection and prompt treatment can prevent sustained conditions and premature death National Heart, Lung, and Blood Institute [4]. Updated evidence-based guidelines for detection and treatment of MetS were established in 2009 between the International Diabetes Federation [5], the National Institutes of Health (NIH), and the World Health Organization (WHO) [6]. Even with clear diagnostic criteria and treatment recommendations, provider adherence and patient compliance behaviors are not acceptable [2].

## **Purpose**

The purpose of this Quality Improvement Project was to implement a process to address the negative metabolic changes in underinsured patients with MetS. This project aimed to evaluate the effectiveness of a Mediterranean diet and exercise protocol on weight, body mass index (BMI), lipid levels, glucose and glycated hemoglobin level, physical activity and eating behaviors. The goals for this Project were to restore metabolic abnormalities to healthier and/or normal parameters and increase healthy lifestyle behaviors. Additionally, this Project aimed to initiate a protocol that would be sustainable at the facility for addressing MetS diagnosis and treatment with lifestyle changes. Using evidenced based education, healthy demonstrations, and encouragement could potentially increase healthy behaviors, reduce disease risk, and lower healthcare costs.

## **Procedure Project Design**

This Quality Improvement Project was implemented to determine whether a Mediterranean diet and exercise protocol in an underserved population could be successful. In this project, the effect of a Mediterranean diet and exercise protocol on metabolic function, diet, and physical activity behaviors were measured in the pre-and post- intervention. All outcome variables were measured at time of recruitment, or pre-intervention, and at the three-month follow-up, or post- intervention.

## **Ethical Consideration**

Approval from the Institutional Review Board (IRB) of Southeastern Louisiana University was obtained to ensure human subject protection prior to implementing the project. In addition, the principal investigator gained site approval from the MLK Health Center and Pharmacy executive director. To protect participants, a risk-benefit assessment was completed prior to project initiation. This assessment highlighted the Projects beneficence at the individual and societal level. Human subject protection training through the CITI program and participant informed consent were completed prior to project implementation. Participant records remained confidential.

## **Data Collection**

Each voluntary participant completed a demographic sheet, including age, gender, race, ethnicity. Afterwards, participant lifestyle habits were assessed using the self-administered Mediterranean Diet Adherence Screener (MEDAS) and International Physical Activity Questionnaire (IPAQ) forms were completed. The MEDAS was developed and validated for the PREDIMED study and provides rapid estimation of Mediterranean diet adherence which measures eating behaviors in this project [7]. Correlations between the MEDAS and nutrient intake on a 137-item food frequency questionnaire indicated reasonable construct validity ( $r = 0.52$ ) [8]. The MEDAS consists of twelve questions on food consumption frequency and two questions on food intake habits characteristic of the Mediterranean diet. Each question is scored a 1 for food consumption or habits closely related to the Mediterranean diet or a 0 for not. A score of 0 to 14 will be given on the MEDAS. A score greater than or equal to 9 means compliance with the Mediterranean diet. The IPAQ was developed for cross-national monitoring of physical activity and inactivity in 2000. An activity score is calculated and categorized as inactive, minimally active, or Health-Enhancing Physical Activity (HEPA) active.

Questionnaires were completed and collected prior to diet and exercise protocol educational sessions at the first and three month follow up sessions. Trained staff members measured blood pressure, height, weight, waist circumference, glycosylated hemoglobin, glucose, and lipid panel and documented results in each patient chart. The principal investigator collected this data from each paper chart and recorded it on a Scores & Metabolic Markers Collection Form.

Demographic forms and questionnaires were placed in a sealed envelope in a locked drawer with a self-identifiable code. This information was then entered in an Excel spreadsheet according to self- identifiable code. This spreadsheet was kept on a password protected laptop accessible only to the principal investigator.

## **Setting**

The setting for the project was the Martin Luther King (MLK) Health Center and Pharmacy in Shreveport LA. MLK Health Center and Pharmacy is a community safety net clinic. The clinic provides chronic disease management at no charge to underinsured adults [10].

## Participants

The convenience sample was recruited from patients enrolled for free care at MLK Health Center and Pharmacy. Criteria for voluntary participation included adults with a diagnosis of MetS based on International Diabetes Federation consensus definition [5]. Exclusion criteria included no access to home or cellular phone, inability to give fully informed consent, individuals with no desire to change current diet or physical activity level, and primary language other than English or Spanish. There were no exclusions based on gender, race, ethnicity. An a priori power analysis determined an appropriate target sample size of thirty-four participants.

## Intervention

The intervention was a protocol using the Mediterranean diet along with exercise, nutritional advice, and support sessions for underinsured, adult patients diagnosed with MetS. This intervention was loosely based on the PREDIMED (Prevention with Mediterranean Diet) trial of almost 8,000 participants with Diabetes or  $\geq$  three cardiovascular risk factors in Spain [8]. To begin the first session, each subject participated in a group session. A similar session occurred at the three month follow up appointment. The principal investigator and MLK staff dietician lead sessions which included Mediterranean diet counseling. An educational booklet on beginning the Mediterranean diet was provided in the patient's primary language. Other materials included colorful tip sheets with pictures, simple recipes, information on growing and purchasing Mediterranean foods, saving money by cooking healthier, and how to read a nutrition label. Reading materials were at the level appropriate for fifth grade or above.

Dietary counseling comprised about three quarters of the content and time for the intervention. This section of the session was approximately 30 minutes in length. The rest of the group session was devoted to physical activity counseling with a goal of  $\geq$  30 minutes at least five days a week.

The second part of the Mediterranean Diet and Exercise Protocol is monthly telephone follow up calls. These calls were led with a script and covered the participants' diet and exercise progress. Additionally, questions related to the study were answered using the provided informational materials and participants were encouraged to keep follow up appointments. During the call, the MEDAS questionnaire was completed, and participants were asked how often in the last week they were active for a minimum of 30 minutes. This information was collected for motivational purposes.

The last part of the intervention occurred at the participants three month follow up. This session included Mediterranean diet counseling and exercise encouragement lead by the principal investigator and dietician. An overview of the initial session information as well as seasonal gardening and tips for purchasing seasonal fruits and vegetables was reviewed. Additionally, information was included on how to stay on track with the Mediterranean eating all day and in the future. Lastly, activity routines were discussed which included the continuation of maintaining 30 minutes of exercise at least 5 days a week. Also, tips for performing exercises for free within the home were given.

## Data Analysis

All data was read into the Statistical Analysis System (SAS) version 9.4. Descriptive statistics were used to summarize or characterize essential elements of data. The following demographic data, including their levels of measurement were obtained: age-ratio, gender-nominal, and race-nominal. Descriptive statistics were also included for the markers of metabolic function, all ratio level of measurement: waist circum., HDL, TRIG, HgbA1c, glucose, and blood pressure. These included mean and standard deviation. The pre- and post- test scores on the MEDAS and IPAQ, ordinal data, were analyzed using McNemar's test. Assumptions include a random sample, paired sample, and mutually exclusive groups. A p-value less than or equal to 0.05 means the result is statistically significant.

The categorical variable MEDAS compliance (compliant or non-compliant) was used in the statistical analysis. The short IPAQ asks seven questions about three specific types of activity undertaken in four domains. An activity score was calculated and categorized as 1=inactive, 2=minimally active, or 3=HEPA active.

Inferential Statistics were used to make conclusions from the sample to the population and test hypothesis [11]. A paired samples t-test was used to evaluate the differences in pre- and post-intervention markers of metabolic function. A result was considered statistically significant if  $p < 0.05$ . The effect size using Cohen's d, the mean difference divided by the standard deviation, was also used to measure the size of the difference between means from pre- and post- implementation. The following null and alternative hypothesis were included during testing: H0: There is no difference in mean markers of metabolic function before and after implementation of a Mediterranean diet and exercise protocol. H1: There is a difference in mean markers of metabolic function before and after implementation of a Mediterranean diet and exercise protocol. The following assumptions were required For McNemar's test: all observations must be independent, expected count or cases in each cell should be greater than 1, and no more than 20% of cells should be less than 5.

## Demographics

Descriptive statistics, including mean and percentages, were used to summarize the demographic characteristics of age, gender, and ethnicity. There was a total of twenty seven participants, with an average age of 50.6 years (SD = 11.42), a minimum age of 30 years and a maximum age of 71 years. As shown in (Table 1), the project sample was comprised of 59.3% females and 40.7% males. Most participants were Hispanic (88.9%), with only 11.1% African Americans. Although the power analysis determined samples size was not achieved, all twenty-seven voluntary participants maintained enrollment, for a retention rate of 100%.

## Results

The MEDAS score of the twenty-seven participants was compared before and after intervention implementation. Participant compliance with a Mediterranean diet increased from 29.63% to 51.85% with the Mediterranean diet and exercise protocol. McNemar’s test determined that this increase in compliance was statistically significant ( $p = 0.034$ ). The seven subjects that shifted from non-compliant (pre-implementation) to compliant (post-implementation) was significantly larger than the one subject who shifted from compliant to non-compliant. Participant IPAQ scores were compared pre- and post- intervention. Compliance with at least a minimally active lifestyle increased from 48.15% to 77.78% post-intervention. McNemar’s test of symmetry determined there was not a statistically significant difference in the distribution of activity for study participants pre- and post-intervention ( $p = 0.094$ ). However, results did show an improvement in exercise level in participants who were initially physically inactive. Nine (33.33%) of the 27 subjects improved from inactive (pre- implementation) to minimally active (post-implementation).

The mean, standard deviation, and median for each marker of metabolic function, waist circumference, blood pressure (systolic and diastolic), HDL, triglycerides, glycated hemoglobin, and fasting glucose, were analyzed pre- and post-intervention. Preliminary findings were promising as each variable mean appeared to have improved from pre- to post-intervention, apart from diastolic blood pressure (DBP). The most improved variable was waist circumference with a mean change of -1.52 inches. The second most improved variable was serum triglycerides with a mean reduction of 19.41 mg/dL.

Variable Label	Sample Size	Mean	Standard Deviation	50th Percentile (Median)
Waist Circumference Before Implementation	27	43.96	5.95	45
Waist Circumference After Implementation	27	42.44	5.6	43
Change (Post - Pre) in Waist Circumference	27	-1.52	2.58	-1
SBP Before Implementation	27	130.44	18.85	129
SBP After Implementation	27	129.26	13.51	124
Change (Post - Pre) in SBP	27	-1.19	13.72	-2
DBP Before Implementation	27	77.81	9.03	79
DBP After Implementation	27	78	7.95	79
Change (Post - Pre) in DBP	27	0.19	7.11	0
HDL Before Implementation	27	50.44	18.16	46
HDL After Implementation	27	51.63	13.88	48
Change (Post - Pre) in HDL	27	1.19	7.22	1
Triglycerides Before Implementation	27	212.67	133.41	174
Triglycerides After Implementation	27	193.26	121.69	164
Change (Post - Pre) in Triglycerides	27	-19.41	64.39	-4
Hgba1c Before Implementation	27	7.2	1.33	6.9
Hgba1c After Implementation	27	7.02	1.45	6.8
Change (Post - Pre) in Hgba1c	27	-0.18	1.04	-0.1
Fasting Glucose Before Implementation	27	162.59	58.14	161
Fasting Glucose After Implementation	27	154.89	66.83	146
Change (Post - Pre) in Fasting Glucose	27	-7.7	68.59	-6

**Table 1:** Statistical Analysis of Metabolic Markers.

A paired samples t-test was conducted to determine whether markers of metabolic function, waist circumference, blood pressure (systolic and diastolic), HDL, triglycerides, glycated hemoglobin, and fasting glucose, differed pre- and post-intervention. The change between post- to pre-intervention means was used to analyze for statistically significant deviations. Results showed a statistically significant difference in waist circumference pre- to post-intervention ( $p = 0.0051$ ).

Therefore, the null hypothesis was rejected for waist circumference. The effect size for the paired t-test was calculated by dividing the mean difference by the standard deviation of the difference, otherwise known as Cohen's d. The only variable found to have a moderate effect size was waist circumference (Table 2).

Variable	Maximum	Paired T Statistic	P- Value of t Statistic	Effect Size (Cohen's d)	Effect Size Classification
Waist Circumference	3	-3.06	0.0051	-0.59	Moderate
HDL	19	0.85	0.4013	0.16	Small
Triglycerides	134	-1.57	0.1294	-0.3	Small
SBP	24	-0.45	0.6572	-0.09	Small
DBP	15	0.14	0.8934	0.03	Small
Hgbalc	2.3	-0.89	0.3808	-0.17	Small
Fasting Glucose	174	-0.58	0.5645	-0.11	Small

Note: Abbreviations: HDL= High Density Lipoprotein; SBP= Systolic Blood Pressure; DBP= Diastolic Blood pressure

**Table 2:** Statistical Analysis of Metabolic Markers (Paired t-test & Cohen's d).

## Discussion

The sample was found to be almost completely Hispanic (88.9%). Additionally, there was nearly 20% more females (59.3%) compared to males (40.7%). The analysis revealed areas of statistical significance. McNemar's test of symmetry was used to measure whether the changes to the pre- and post- intervention MEDAS and IPAQ were statistically significant. Analysis showed the increase in compliance with the Mediterranean diet was statistically significant from pre- to post- MEDAS ( $p = 0.034$ ). Additionally, the paired t-test showed statistical significance of the mean differences between pre- and post-intervention waist circumference ( $p = 0.0051$ ). The effect size was also deemed to be moderate for waist circumference. Interestingly, the only variable that did not improve post-intervention was the diastolic blood pressure. Conversely, the IPAQ, systolic blood pressure, HDL, triglycerides, Hgbalc, and fasting glucose results did show improvement but not a statistically significant difference between pre- and post-intervention levels after implementation of the Mediterranean diet and exercise protocol.

## Recommendations

Evidence is clear that the metabolic risk factors for cardiovascular disease due to MetS should be treated aggressively. Individuals from vulnerable populations are at higher risk for developing MetS due to lack of resources and socioeconomic status. Many vulnerable individuals seek care in primary care safety-net clinics such as MLK Health Center and Pharmacy. The MLK Health Center and Pharmacy vision is to improve the health of the community it serves while meeting the demand for high quality comprehensive healthcare services in a cost effective, patient centered manner. Although services are at no cost to uninsured patients with chronic illnesses, adopting healthy lifestyle behaviors can be difficult. Socioeconomic and cultural factors can make implementation of a lifestyle change more difficult.

The project findings were significant for MLK Health Center and Pharmacy. MLK Health Center and Pharmacy did not have a lifestyle protocol in place for patients diagnosed with MetS prior to the implementation of the DNP project. Statistically significant findings were demonstrated in compliance with a Mediterranean diet and with waist circumference three months post- implementation. With a longer duration, more statistically significant findings were expected based on improvement in other metabolic markers and improved physical activity scores. If adopted as a method to prevent and treat metabolic syndrome and its risk factors, the Mediterranean diet and exercise protocol would be the first of its kind at MLK Health Center and Pharmacy.

To improve and sustain the project, an EMR system could be incorporated at MLK Health Center and Pharmacy. This would vastly improve the identification and monitoring of patients with MetS. Screening checklists for diagnosing MetS, lifestyle questionnaires, and monitoring of MetS criteria could be embedded in an EMR. Using this technology for trending patient data could improve long term health outcomes. The DNP project could have different outcomes if completed with a larger sample over a longer duration. There are many feasible ways to continue improving the project and enhancing its sustainability over time. The project's encouragement of an EMR system at the facility was an unexpected discovery. The dedicated staff and the population at MLK Health Center and Pharmacy make the facility an excellent candidate for sustained use of the Mediterranean diet and exercise protocol.

### **Conflict of Interest**

The author declares there are no financial or commercial relationships that could constitute potential conflicts of interest in the conduct of the research.

### **References**

1. Centers for Disease Control and Prevention (CDC) (2020) Hispanic/Latino Americans and Type 2 Diabetes. Centers for Disease Control and Prevention.
2. Deen D (2004) Metabolic syndrome: Time for action. *American Family Physician* 69: 2875-2882.
3. Curtis LH, Hammill BG, Bethel MA, et al. (2007) Costs of the metabolic syndrome in elderly individuals: findings from the cardiovascular health study. *Diabetes Care* 30: 2553-2558.
4. National Heart, Lung, and Blood Institute (NIH) (2019) Metabolic Syndrome. National Institutes of Health.
5. International Diabetes Federation (IDF) (2006) The IDF consensus worldwide definition of the metabolic syndrome.
6. Meigs J (2020) Metabolic syndrome (Insulin resistance syndrome or syndrome X). UpToDate (Version 37.0) [Mobile App].
7. Schroder H, Fito M, Estruch R, et al. (2011) A short screener is valid for assessing Mediterranean diet adherence among older Spanish men and women. *The Journal of Nutrition* 141: 1140-1145.
8. Martinez-Gonzalez MA, Garcia-Arellano A, Toledo E, et al. (2012) A 14-item Mediterranean diet assessment tool and obesity indexes among high-risk subjects: The PREDIMED trial. *PLOS ONE* 7: E43134.
9. Martin Luther King (MLK) Health Center and Pharmacy (2020) Our mission.
10. Kim M, Mallory C (2017) *Statistics for evidence-based practice in nursing* (2nd edition) Jones & Bartlett Learning.