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Barriers to Nutrition Counseling with a Registered Dietitian (RD) and Its Association with Dietary Intake, Nutrition Status, Disease Outcomes and Substance Abuse in People Living with HIV (PLWH).

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BARRIERS TO NUTRITION COUNSELING WITH A REGISTERED DIETITIAN (RD), AND ITS ASSOCIATION WITH DIETARY INTAKE, NUTRITION STATUS, DISEASE OUTCOMES AND SUBSTANCE ABUSE IN PEOPLE LIVING WITH HIV (PLWH).

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by

Christina D. Fleetwood

To: Interim Dean Mark Williams
R. Stempel College of Public Health and Social Work

This dissertation, written by Christina D. Fleetwood, and entitled Barriers to Nutrition Counseling with a Registered Dietitian (RD), and Its Association with Dietary Intake, Nutrition Status, Disease Outcomes and Substance Abuse in People Living with HIV (PLWH), having been approved in respect to style and intellectual content, is referred to you for judgment.

We have read this dissertation and recommend that it be approved.

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The dissertation of Christina D. Fleetwood is approved.

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DEDICATION

I dedicate this dissertation to my family and friends who have been a constant source of support and encouragement during the challenges of graduate school and life. This work is also dedicated to my late parents, Kenneth and Carolyn Fleetwood, who taught me to work hard for the things that I aspire to achieve.

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ABSTRACT OF THE DISSERTATION

BARRIERS TO NUTRITION COUNSELING WITH A REGISTERED DIETITIAN (RD) AND ITS ASSOCIATION WITH DIETARY INTAKE, NUTRITION STATUS, DISEASE OUTCOMES AND SUBSTANCE ABUSE IN PEOPLE LIVING WITH HIV (PLWH).

by

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The relationship between nutrition and HIV is multifactorial. Nutrition counseling provided by a Registered Dietitian (RD) has the potential for improving disease risk outcomes for PLWH. To determine barriers to access nutritional counseling with an RD in PLWH, and evaluate the relationship of this counseling on dietary intake, nutritional status, cardiovascular disease (CVD), and HIV-disease outcomes.

This is a cross-sectional study of a consecutive convenience sample of 130 PLWH on stable ART from the MASH cohort. After consenting, participants completed a survey on types and frequency of nutritional services received in the last 12 months, and on barriers to access these services. Participants were assigned to groups according to their responses. Demographics, anthropometries, dietary intake, medical history and laboratory information were obtained. The Alternative Healthy Eating Index (AHEI) scores were calculated after obtaining two 24-hour dietary recalls, and Nutribase and SPSS 20 were used for analyses.

Mean age was 47.7 years, 62.0% were male and 77.0% were Black; 48% percent were seeing an RD, with 48.3% of those visiting an RD≥4 times within the year. Frequently identified barriers to nutritional services were difficulty in keeping appointments (33.8%) location (24.6%) and lack of referrals (23.8%) by medical personnel. Lack of referral was associated with lower CD4 cell count (r=-0.2, P=0.029). Compared to those who did not visit an RD, participants who did had higher AHEI scores (34.7 vs. 29.2, $P < 0.001$), lower waist circumference (35.5 vs. 38.5 in., P=0.003), and BMI (26.0 vs. 28.8 kg/m^2, P=0.019), with higher proportion of participants within the normal range of BMI (48% vs. 25%, P=0.017). The group consulting an RD had significantly lower risk factors for CVD, with better lipid profiles for all biomarkers, and lower waist circumference (35.5 vs. 38.5 inches, $P = 0.003$) and systolic blood pressure (114.8 vs. 127.9 mmHg, $P < 0.001$). Other CVD risk factors such as ART and substance abuse, common in this population, were not significantly different between the groups. Our findings suggest that consulting with an RD is associated with better nutritional status, dietary intake and lower risk factors for CVD.

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ABBREVIATIONS AND ACRONYMS

AHEI	Alternate Healthy Eating Index
AIDS	Acquired Immunodeficiency Syndrome
AND	Academy of Nutrition and Dietetics
ART	Antiretroviral Therapy
BIA	Bioelectrical Impedance
BMI	Body Mass Index
CDC	Center for Disease Control and Prevention
CHD	Coronary Heart Disease
CI	Confidence Interval
CVD	Cardiovascular Disease
FFM	Fat-Free Mass
FRS	Framingham Risk Score
GI	Gastrointestinal Tract
HAART	Highly Active Antiretroviral Therapy
MASH	Miami Adult Studies on HIV
HDL	High-Density Lipoprotein
HEI	Healthy Eating Index
Hgb	Hemoglobin
HIV	Human Immunodeficiency Virus
HOMA	Homeostatic Model Assessment
IDU	Intravenous Drug User
LDL	Low-Density Lipoprotein
MetS	Metabolic Syndrome
MI	Myocardial Infarct
MSM	Men who have sex with men

NFHL	Nutrition for Healthy Living
NHANES	National Health and Nutrition Examination Survey
UNAIDS	Joint United Nations Program on HIV/AIDS
OR	Odds Ratio
PLWH	People Living with HIV
RD	Registered Dietitian
RDA	Recommended Daily Allowance
REE	Resting Energy Expenditure
SMART/EST	Stress Management and Relaxation Training/Expressive-Support Therapy
SNAP	Supplemental Nutrition Assistance Program
USDA	United States Department of Agriculture
WC	Waist Circumference
WHO	World Health Organization

CHAPTER I: INTRODUCTION

Statement of Problem

The Human Immunodeficiency Virus (HIV) causes immunosuppression in those infected with the disease. Adequate dietary intake can support the innate immune system and delay the suppression of the specific immune system.[1] Declines in nutritional status are seen in HIV-positive individuals with secondary infections, furthering immune depletion and progression of the HIV disease.[1,2] Therefore, maintaining HIV-infected patients in adequate nutritional status is an integral part of the long-term management and treatment of HIV disease.[3]

The HIV epidemic is one of the most critical problems in Public Health in our community. Florida has the 3rd largest population of individuals infected with HIV in the United States, and Miami-Dade County has the highest number of cases in the State of Florida.[4,5] The city of Miami also has the greater number of incident cases in the United States.[4,5] Multiple factors foster malnutrition in people living with HIV, including inadequate dietary intake, food insecurity, chronic drug use, and digestive complications caused by a weakened immune system or a side effect of highly active antiretroviral therapy (HAART).[6-8] Deficiencies caused by inadequate dietary intake are associated with unfavorable disease outcomes and poor quality of life.[9,10] Alterations in metabolism requiring additional nutrients further complicate nutritional status in individuals with immune systems that are already compromised.[11] Drug and alcohol use further compromise nutritional status and increase the risk of opportunistic infections.[12,13]

A decrease in energy intake is common among individuals with HIV infection. Due to a weakened immune system, they are prone to infections that can affect the

appetite or the ability to consume food.[14] Problems that have been reported to affect intake include a decline in appetite, lethargy, sores in the mouth, and dysphagia.[15] Adverse side effects of medications such as metabolic abnormalities, gastrointestinal disturbances, and decreased dietary intake lead to poor adherence to therapy and a decline in nutritional status.[16] Furthermore, reported side effects of HAART such as nausea, anorexia, and taste aversions will further complicate dietary intake and compromise nutritional status.[8]

A variety of gastrointestinal problems can also impact food intake. Upper gastrointestinal problems such as nausea or vomiting or lower gastrointestinal problems such as diarrhea or constipation are common in individuals with HIV infection.[15,17] Continued gastrointestinal complications can lead to malabsorption, which can further impact malnutrition and weight loss. Malnutrition can further compromise the integrity of the digestive tract and exacerbate weight loss in addition to compromising the innate immune system, it accelerates and deepens immune deficiency.[19]

Nutritional support for individuals on HAART can improve nutritional status and health outcomes by improving dietary intake in those infected with HIV.[2] A balanced diet is critical in HIV infection because it supports the immune response and promotes health. The Academy of Nutrition and Dietetics (AND) recommends HIV-infected individuals to seek the services of a Registered Dietitian (RD) on a routine basis.[3] An RD is a nutrition professional who has met the educational and practical standards set forth by the Commission on Dietetic Registration (CDR) of the Academy of Nutrition and Dietetics (AND). HIV-infected persons should see a clinical dietitian, these RD's are specially trained to provide medical nutrition therapy (MNT), which includes the

development of a dietary plan incorporating nutritional education and dietary counseling.[3]

Multiple factors have been identified that influence adherence to HIV treatment. The two most commonly identified barriers to receiving healthcare in this population include lower literacy and education levels.[18,19] Although several studies have identified barriers to access to food such as lack of a caregiver, transportation, assistance with shopping for food and preparation of food.[20] Few studies have focused on barrier to receiving nutritional counseling and consuming an adequate dietary intake. Therefore, this research study was implemented to evaluate the barriers that impede HIV-positive individuals from receiving nutritional support from an RD. Furthermore, we propose that nutritional counseling with an RD will improve dietary intake and nutritional status of HIV-positive individuals compared to those who are not receiving nutritional counseling.

Significance of the proposed study

The relationship between inadequate dietary intake and HIV infection is multidirectional. HIV infection can impact dietary intake and lead to malnutrition, which in turn leads to an increased need for additional nutrients.[11] Malnutrition weakens the immune system, increasing the risk of secondary infections.[1] Improvements in dietary intake provided by nutritional counseling with an RD improve the outcomes in PLWH.[21,22] While the Academy for Nutrition and Dietetics does acknowledge the importance of nutritional counseling with an RD, a review of current literature did not find any studies that specifically monitored the benefits for individuals who attend nutritional counseling sessions. The purpose of this study is to determine the barriers that affect dietary intake and attendance of nutritional counseling sessions with an RD in

HIV-positive individuals living. The secondary aim of this study is to investigate the relationship of nutritional counseling by an RD's on dietary intake, nutritional status, disease outcomes, and CVD in the HIV population compared to individuals not receiving nutritional counseling.

Specific Aims and Hypotheses

Specific Aims 1: To examine the barriers that impact the attendance of nutritional counseling sessions with an RD and determine if medical and ancillary personnel create additional external barriers to treatment.

Hypothesis 1a: There will be a significant difference in the barriers perceived by individuals who are currently attending nutritional counseling with an RD compared to those who have not seen an RD.

Hypothesis 1b: Medical and ancillary personnel are lacking information regarding dietary services, creating additional barriers for the successful referrals of patients to RD's for nutritional counseling.

Rationale

The barriers to attending and adhering to nutritional counseling sessions with an RD are not well documented in the HIV-infected population. Understanding the barriers preventing individuals from attending and utilizing the information provided during nutritional sessions is important for the HIV-infected community to help improve health outcomes by improving dietary intake. Nutritional services are available through various federal and state programs, such as the Ryan White program, at a reduced cost or free, depending on financial stability.[3] Furthermore, medical and ancillary workers that are in contact with HIV-positive individuals are vital to the success of nutritional services

programs. Assessing the knowledge of these employees is important to determine their awareness about nutritional services offered and to determine the barriers preventing the referrals of patients to an RD. This information will help to identify additional barriers to nutritional counseling that individuals with HIV might face.

Specific Aim 2: To investigate the relationship of nutrition counseling by an RD with dietary intake (assessed by 24-hr food recalls and the alternate healthy eating index (AHEI), nutritional status (assessed by BMI, waist-hip ratio, BIA, hemoglobin, hematocrit, albumin, fasting glucose, plasma levels of zinc and selenium) and disease outcomes (assessed by CD4 cell counts and viral loads) in HIV-infected adult men and women who received nutritional counseling from an RD compared to individuals who are not receiving counseling from an RD.

Hypothesis 2a: The group that received nutrition counseling by an RD have better dietary intake in HIV-positive individuals compared to those HIV-positive individuals who are not seeing an RD.

Hypothesis 2b: The group that received nutrition counseling by an RD have better anthropometric measurements in HIV-positive individuals compared to those HIV-positive individuals who are not seeing an RD.

Hypothesis 2c: The group that received nutrition counseling by an RD have better nutritional status measured by laboratory parameters in HIV-positive individuals compared to those HIV-positive individuals who are not seeing an RD.

Hypothesis 2d: The group that received nutrition counseling by an RD have better disease outcomes in HIV-positive individuals compared to those HIV-positive individuals who are not seeing an RD.

Rationale

Evidence regarding the benefits of individualized nutrition counseling provided by an RD for HIV-infected individuals is insufficient; therefore this study serves to bridge this gap in literature. RD's use basic nutritional assessments to determine the nutritional status of the patient.[23] Anthropometric changes are used as parameters of nutritional status in people living with HIV because they are inexpensive and non-invasive.[24] Body composition measurements are used to monitor fat redistribution, which is common in individuals on HAART, and increase risk of comorbidities such as cardiovascular disease (CVD) and diabetes.[23,25-27] One common method used to determine fat redistribution is with measurements of the circumferences of the waist and hip.[23] The ratio provides a good indicator of body composition, ratios greater than 0.85 in females and 0.95 in males indicate risk for CVD or diabetes.[23,24] The additional information that the BIA provides, such as body cell mass, fat-free mass, and total body water is also helpful for determining nutritional status. [24] Biochemical parameters or biomarkers, add a further detailed characterization of the nutritional status. General nutrition status can be assessed using laboratory assessments of albumin and fasting glucose.[23,24,28,29] Hemoglobin and hematocrit are commonly measured variables included in basic blood work and are useful for monitoring HIV infection and in determining iron status.[9,30] Zinc and selenium have major role in maintaining a healthy immune system,

deficiencies of these two antioxidants contribute to immune dysregulation and viral replication.[31,32]

Specific Aim 3: To investigate the relationship of nutrition counseling by an RD with cardiovascular disease (CVD) and metabolic syndrome (MetS), risk factors and the 10-year risk of cardiovascular disease (determined by the Framingham Risk Score) in HIV-infected men and women who received nutritional counseling by an RD compared to individuals who are not seeing an RD.

> ***Hypothesis 3a:*** The group that received nutrition counseling by an RD has reduced risk factors for CVD and metabolic syndrome in HIV-positive individuals compared to those HIV-positive individuals who are not seeing an RD.
>
> ***Hypothesis 3b:*** The group that received nutrition counseling by an RD has a reduced 10-year risk for cardiovascular disease in HIV-positive individuals in Miami-Dade County compared to those HIV-positive individuals who are not seeing an RD.

Rationale

CVD has become the leading cause of non-AIDS-related deaths in HIV-infected persons.[33] Metabolic complications related to antiretroviral therapy (ART) have been shown to increase the risk of CVD risk factors such as dyslipidemia, hypertension, and diabetes.[34] HIV-infected patients are subject to the same traditional CVD risk factors as HIV-negatives, which include diet.[35]

Table 1: Summary of statistical analysis					
Hypothesis	**Independent Variables**	**Dependent Variables**	**Assessments**	**Type of Variable**	**Statistics**
1a Barriers	RD History	Barriers	Questionnaire	Continuous Categorical	Barriers were described using means and standard deviation. Student t-tests and chi-square were be used to determine differences in barriers between groups. Spearman rank correlations were used to estimate associations between identified barriers and other categorical outcome variables that affect attendance with an RD.
1b Barriers	RD History	Barriers	Questionnaire	Categorical	Barriers were described using means and standard deviation.
2a Dietary Intake	RD History	AHEI-Score Calories Protein Carbohydrate Fiber Total Fat Saturated Fat Zinc	24-Hour Food Recalls AHEI-2010	Continuous	AHEI scores will be described using means and standard deviation. Student t-tests were used to determine if nutritional counseling is associated with changes in the AHEI score. Linear regression models were used to compute the Beta (β). Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.
2b Anthropometrics	RD History	BMI Waist-hip ratio Fat Mass Fat % BCM BCM %	Anthropometric BIA	Continuous Categorical	Nutritional status variables will be described using means and standard deviation. Student t-tests and chi-square will be used to compare differences in the groups related to nutrition counseling. Linear regression models were used to compute the Beta (β). Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.

2c Laboratory	RD History	Hemoglobin Hematocrit Albumin Fasting Glucose Zinc Selenium	Laboratory	Continuous Categorical	Linear regression models were used to compute the Beta (β). Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.
2d Disease Progression	RD History	CD4 Cell Counts Viral loads	Laboratory Reports	Continuous Categorical	Student t-tests and chi-square will be used to determine if nutritional counseling is associated with changes in CD4 cell counts and viral loads. Linear regression models were used to compute the Beta (β). Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.
3a MetS	RD History	MetS	Anthropometric Clinical Laboratory	Continuous	Student t-tests was used to determine if nutritional counseling is associated with differences in MetS between the two groups. Linear regression models were used to compute the Beta (β). Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.
3b CVD Risk	RD History	10-Year Risk	Clinical Demographic Drug Use Questionnaire Laboratory	Continuous Categorical	Student t-tests and chi-square will be used to determine if nutritional counseling is associated with differences in alcohol consumption and drug usage between groups.

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CHAPTER II: LITERATURE REVIEW

HIV Epidemiology

The human immunodeficiency virus (HIV) targets the body's immune system. The virus destroys CD4 cells, which act by helping the body to fight infection. The period of disease progression from infection to death lasts between 4-20 years, depending on HIV-subtype, environmental, and socioeconomic conditions surrounding people living with HIV (PLWH).[1] The virus disables the lymphatic immune system; gradually the patients becomes immunodeficient. The most advanced stage of HIV is known as AIDS, which stands for acquired immunodeficiency syndrome. In the final stage of AIDS, the virus eventually begins to destroy the CD4+ T-cells, which are supposed to suppress the virus of the hosts' immune system, followed by death.[1] Several global organizations, such as the Joint United Nations Program on HIV/AIDS (UNAIDS), World Health Organization (WHO), and the United States Center for Disease Control and Infection (CDC) are responsible for monitoring the disease and providing leadership in research and development.[2] This global approach to the HIV epidemic initiated the new concept and discipline Global Public Health.[2] These organizations have the responsibility to produce current statistics and standards of care,[2] which includes nutritional interventions for PLWH.

WHO estimated that as of 2013, there were 35 million people globally living with HIV.[3,4] Of this estimate, 19 million were not aware of their HIV status.[4] Since 2001, the rate of new infections has declined 38% while the rate of AIDS-related deaths has also fallen 35%.[4] However, since the beginning of the epidemic it is estimated that 39 million people have died from HIV/AIDS-related deaths.[3,4] Despite the advances in treatment, as

of 2013, only 37% of persons living with HIV were receiving antiretroviral therapy (ART).[3,4]

According to the Center for Disease Control and Prevention (CDC) the number of individuals in the United Stated living with HIV has increased over the past decade.[5] Currently, it is estimated that 1.2 million individuals are HIV-positive, with an estimated 168,300 additional people who are unaware of their HIV-positive status.[5] Annually the number of new HIV cases remains stable with an estimated 50,000 individuals diagnosed yearly.[5] Individuals affected the most by HIV include men who have sex with men (MSM), bisexuals and gays.[5] The spread of HIV among MSM is a major concern, with a reported 12% increase in 2010 with 29,800 new cases, accounting for the largest increase in new infections. Racial disparities are prevalent in the HIV population, with the majority of HIV cases reported in the Black and Hispanic population. In 2010, Blacks accounted for 44% of new HIV cases and 41% of total HIV cases in 2011.[5] Hispanics accounted for 21% of new HIV cases in 2010 and 20% of total cases in 2011.[5] The rate of new infections in Hispanic males was 2.9 times that for Caucasian males, while the rate for Hispanic females was 4.2 times that for Caucasian females.[5]

The State of Florida has one of the highest numbers of HIV cases in the United States with a total of 107,760 total HIV/AIDS reported the beginning of 2015.[6] The prevalence of HIV has become a major public health issue in Florida, which reported 5,697 new HIV cases in 2014 and 2,521 new AIDS cases.[6] Within the State of Florida, Miami-Dade County ranks the highest in both HIV and AIDS reported cases.[6] As of February of 2015, there were an estimated 27,722 HIV/AIDS cases in Miami-Dade County.[6] Reported incidence of new cases has been declining in Miami-Dade County

over the past 3 years. In 2014, there was a 1% increase in HIV cases in Miami-Dade with 1298 new cases, and a decrease of 25% for new AIDS cases with 483 reported.[6]. Miami is the city with the highest incidence of HIV in the United States. Similarities have also been seen in racial disparities in new cases; 58.7% of new cases reported in males were in Hispanic males while the females had 67.1%.[5,6]

HIV Disease and Nutrition

Malnutrition has been associated with a weakened immune system and disease progression in individuals with HIV.[7-10] The immune impairment caused by HIV leads to malnutrition and contributes to the rapid progression of HIV. Nutritional deficiencies and dietary related effects are commonly seen in individuals that have progressed to AIDS.[11-13] Malnourished individuals are more likely to progress faster to AIDS due to the bodies weakened ability to fight infection.[12,13] Adequate dietary intake has been shown to increase resistance to infection and disease in HIV-positive individuals. Sharkey et al.[8] found a linear relationship between disease progression and dietary intake with inadequate intake of energy, carbohydrate, and dietary fiber correlating with lower CD4 cell counts. Furthermore, a decline in weight, body mass index (BMI) and body composition was associated with faster HIV disease progression reflected in reductions in CD4 cell counts.[8] Monitoring CD4 cell counts and viral loads provides information on HIV disease progression and response to intervention.[14] While CD4 cell counts are essential for providing information regarding the severity and progression of the disease, HIV viral load provides information about the number of HIV viruses per mL of blood.[8] Untreated HIV infection is characterized by high levels of HIV viral load, which facilitates decline of CD4 cell count.[3] The goal of any HIV treatment program is to

reduce HIV viral load to undetectable levels and increase CD4 cell count.[3] Nutritional interventions have been shown to improve the immune system, slow the progression of HIV disease and lower the risk of mortality.[15,16] Furthermore, daily multivitamin and mineral usage has been associated with a significant reduction in progression to AIDS and a reduced risk for low CD4 counts.[17]

Malnutrition

Malnutrition due to inadequate dietary intake is common in the HIV-infected population. Malnutrition is the state of nutrition in which a deficiency or excess of macro- or micronutrients causes adverse effects on the body's function and clinical outcomes.[18] In HIV-positive individuals malnutrition can be a result of infection with the virus or one of the numerous HIV-associated complications.[7,11,13] Other common causes of malnutrition in HIV-positive individuals include inadequate dietary intake, nutrient malabsorption, and metabolic alterations.[7,19-22] An early approach to nutrition support has been suggested for HIV-positive individuals for the prevention, detection, monitoring and treatment of malnutrition.[11]

HIV increases oxidative stress,[23] which in turn is believed to play a significant role in disease progression in HIV-positive individuals. Zinc and selenium, both antioxidants, have been identified for their part in maintaining the immune system. Khalili et al.[24] found that HIV-positive individuals were likely to have a zinc and selenium deficiency compared to those who were HIV-negative. Seventy-seven percent of the HIV-positive group had some degree of malnutrition, with 53% having moderate to severe malnutrition measured by low serum levels of zinc and selenium.[24] Decreases in selenium levels have been associated with decreases in CD4 cell counts and faster HIV

disease progression.[25] Zinc deficiencies were found in 65% of the HIV-positive adults, and 38% of that same group had a deficiency of selenium.[24] Zinc concentrations typically decline during times of infections, which makes individuals who are HIV-positive more prone to zinc deficiencies. Baum et al.[25] found that zinc deficiency, decreased dietary intake, and excess zinc supplementation was correlated with a reduced CD4 cell counts and participant survival. Among HIV-positive drug users, dietary intake of zinc was deficient in 86% of the sample and 56% had inadequate plasma zinc levels. [25] After an 18-month trial with supplementation of zinc HIV positive individuals showed a 4-fold reduction in immune failure.[16]

Nutritional Status

Malnutrition causes immunosuppression and increases the body's susceptibility to opportunistic infections,[26,27] reducing the body's capacity to fight disease and secondary infections. Untreated HIV infection is commonly associated with signs of severe weight loss, which becomes more acute in the advanced stages of disease progression.[12] The cause of this weight loss in the HIV-infection population is multifactorial. A retrospective analysis conducted in the United States on individuals who were not on antiretroviral therapy showed that the differences in weight loss were gender-dependent with women losing more fat than men when compared to HIV-non-infected controls.[28] Whereas other studies found that weight loss was associated with the loss of fat in women, however in men the association was stronger with the loss of body cell mass.[29] Forrester et al.[30] used bioelectrical impedance (BIA) to monitor changes in body composition and found that observed changes in body composition in men were dependent on initial fat percent while no relationship was found in females.

HIV treatment consists of highly active antiretroviral drugs therapy (HAART), which helps to control infection and manage wasting. HAART entails a combination of a minimum of three drugs that suppress the replication of the HIV virus.[31] The combination of drugs reduces mortality rates among HIV-infected individuals by reducing viral load and improving the function of the immune system, reducing the incidence of secondary infections and prolonging survival time in HIV-positive individuals.[31] The purpose of the treatment is to decrease the amount of the HIV virus in the body to a level that cannot be detected in the blood.[31] The use of ART has increased life expectancy for HIV-positive individuals, making HIV infection a chronic disease. The Stress Management and Relaxation Training/Expressive-Support Therapy (SMART/EST) study showed that interruption of antiretroviral treatment was associated with an 80% increase in risk for mortality compared with continuous treatment.[32] Furthermore, discontinuation of treatment was also associated with a 70% increase in risk for comorbidities such as CVD, renal or hepatic disease.[32]

Nutritional status prior to beginning antiretroviral therapy and within the first 3 months is strongly correlated with mortality.[33] Individuals who had BMI's below 17.0 kg/m^2 were at a 2-fold increased risk for death compared to those with normal baseline BMI's.[33] Weight loss and changes in body composition within the first 3-months increased the likelihood of mortality.[33] In HIV-positive individuals a weight loss greater than 10% of their body weight is considered an AIDS-defining characteristic.[34] In the absence of other related illnesses, a weight loss of greater than 10% is called the wasting syndrome.[34] Wasting, which has been associated with a 4 to 6-fold increase in mortality, is also accompanied by chronic fever, weakness, or diarrhea.[35] The prevalence of

wasting in HIV-positive individuals has declined significantly in the United States as HAART has become more widely available; however, weight loss remains a significant predictor of mortality in HIV-positive individuals.[35] With antiretroviral therapy new issues are arising as the prevalence of overweight and obesity.[36] Common factors associated with increases in BMI's include recent HIV diagnosis and lower BMI's at the time of diagnosis.[36] As the prevalence of obesity in the HIV-infected population increases, so does incidence of obesity and related co-morbidities.[37] Dietary trends recognized in obese HIV-positive individuals indicated that these individuals consumed excessive amounts of saturated fat and percentage of calories from fat.[38]

The use of HAART has brought about another problem called lipodystrophy. This involves the redistribution of fat typically from the face and limbs to abdomen, buttocks, or the back.[39] Increases in visceral adipose tissue in the abdomen is associated with increased CD4 counts and a decrease in HIV viral load.[40] The Study of Fat Redistribution and Metabolic Change in HIV Infection reported an increased risk of mortality with an increase in visceral adipose tissue and a decrease in fat in the extremities.[41] Redistribution of fat and metabolic abnormalities associated with HAART have an estimated prevalence of approximately 35% to 44%. [42] Increases in carbohydrate oxidation along with decreases in lipid oxidation have been identified in those with lipodystrophy.[22] Moreover, individuals with lipodystrophy had a 9-25% higher resting energy expenditure (REE) compared to HIV-infected individuals without lipodystrophy.[22,43] A similar study examined cardiovascular parameters in individuals with HIV currently adhering to an HAART regimen and found that those with lipodystrophy had increased triglycerides, LDL cholesterol, HOMA and insulin levels.[44]

Fortunately, dietary and medical interventions have been successful in preventing abnormal amounts of lipid levels also known as dyslipidemia.[45,46] HIV-positive individuals who received dietary counseling reported consuming less fat, which reduced triglyceride levels from 135 mg/dl to 101 mg/dl.[46] A follow-up after one year showed that only 21% of the dietary intervention group continued to have dyslipidemia compared to 68% of the patients in the control group.[46] Furthermore, dietary interventions along with exercise were shown to reverse both metabolic and body composition changes associated with lipodystrophy.[47] A reduction in both subcutaneous and visceral adipose fat was significant with dietary and exercise interventions.[48] To promote a healthy nutritional status and development of an effective nutrition intervention program, monitoring changes in body composition in HIV-positive individuals is imperative.

As antiretroviral therapy (ART) has made HIV infection a chronic disease, metabolic complications such as CVD has been seen with increasing frequency among HIV-positive individuals on treatment.[49] With therapy, the HIV-related deaths have decreased; however, as the population ages, CVD has become a primary cause of non-HIV-related deaths. HIV-positive individuals were 5 times more likely to die within one year following a myocardial infarction (MI) compared to HIV-negative individuals.[50] The increased prevalence of CVD is multifactorial involving use of ART (which has been known to contribute to an increase in CVD risk by 16%), and lifestyle factors.[49] Lifestyle factors including dietary intake, lack of physical activity, smoking, alcohol and other illicit drugs increase the risk of CVD in HIV-infected individuals whose HIV infection is treated.[49] Modifications of these risk factors including dietary changes and a substance

abuse program should be aimed at reducing the risk of CVD. Prescription drug therapy is often necessary for the treatment of CVD risk factors in HIV-positive individuals.

Metabolic factors have been attributed to the increase in CVD rates in HIV-positive individuals.[51] As the HIV-infected population under treatment ages, traditional CVD risk factors including hypertension, dyslipidemia and diabetes are increased, and account for a 25% increase in cardiac risk.[52] The prevalence of diabetes in the Multicenter AIDS Cohort Study was higher among HIV-positive individuals on ART (14%) compared to those that are ART-naive (7%), while the prevalence of diabetes among HIV non-infected individuals was estimated at 5%.[53] An increase in triglyceride levels is often the most pronounced lipid abnormality in HIV-positive individuals.[54] Short-term ART has been associated with a decrease in HDL levels and an increase in total cholesterol levels.[51] While continuous ART for more than 3 years was associated with dyslipidemia, increases were seen in triglyceride, total cholesterol and LDL cholesterol levels.[55] An 11% increased risk of having an MI was associated with each 2-fold increase in triglycerides.[56] When waist circumference is increased along with triglycerides, the risk of insulin resistance, metabolic syndrome, and CVD risk measured by Framingham Risk Score increases.[57] The Framingham Risk Score incorporates the traditional CVD risk factors such as age, gender, smoking status, total and HDL cholesterol, and blood pressure to predict the 10-year risk of MI. De Socio et al. [58] estimated the mean 10-year risk for CVD was 7.4 in an HIV-infected cohort on ART, with the main risk factors identified as smoking, lipodystrophy and higher CD4 cell counts.

Metabolic syndrome is common in HIV-positive individuals on treatment, with a prevalence in various studies ranging from 7.0%-45.5%.[56] Metabolic syndrome is a term that is used to describe a cluster of risk factors for CVD and diabetes, including obesity, hypertension, dyslipidemia, and insulin resistance.[59,60] When 3 of the following 5 conditions have been met, then an individual has metabolic syndrome: hypertriglyceridemia, low HDL cholesterol, hypertension, abdominal obesity and elevated glucose levels.[61] The combination of these comorbidities increases the person's susceptibility to conditions such as CVD and type 2 diabetes.[61] Dietary interventions have been shown to decrease cardiovascular risk factors associated with metabolic syndrome in HIV-positive individuals.[62] Adherence to a Mediterranean-style diet improves CVD risk factors such as HDL cholesterol and triglyceride levels.[62]

Dietary Intake

In HIV-positive individuals there are multiple factors that can affect dietary intake. Clinical symptoms of untreated HIV infection interfere with adequate food consumption including odynophagia, dysphagia, nausea, and vomiting.[7,11] Anorexia is another cause of decreased food intake, which is more common in symptomatic individuals.[63] Individuals with loss of appetite also had altered anthropometric measurements such as weight loss, lower BMI, and lower arm and muscular circumference.[63] In addition, many HIV-positive persons may have limited access to a sufficient supply of nutritious food, limited ability to prepare the food or lack the knowledge about food purchase and preparation.[7]

Food insecurity

Food insecurity is a major contributor to malnutrition in HIV-positive individuals and is associated with HIV-related morbidity and mortality.[64,65] Food-insecure individuals have limited access to nutritionally adequate and safe food or the inability to procure foods that are personally acceptable in a way that is socially acceptable. [66] Among HIV-positive individuals the prevalence of food insecurity is estimated to be 5 times more than the United States national estimates, with current estimates for HIV-infected individuals ranging from 42.7-53.6%. [67,68] Among HIV-positive individuals poverty and low socioeconomic status, such as unemployment, unstable housing, and lack of health insurance strongly correlated with food insecurity.[69,70] Due to sex discrimination, women have been reported to be the most affected by food insecurity and poverty.[67] Food-insecure individuals are also more likely to have a history of intravenous drug use, alcohol or other drug addictions.[69,70]

Compared to HIV-positive individuals who reported food security, those who disclosed insecurity had worse health outcomes.[69-71] Food insecurity was associated with nutritional deficiencies, higher HIV viral loads, and lower CD4 cell counts, with food insecure individuals being twice as likely to die.[69-71] Food insecurity was also associated with poor adherence to HIV therapy and other medications.[69-71] Twenty-five percent of HIV-positive individuals reported having to choose between purchasing food or medications.[71] The interaction between HIV disease progression, malnutrition, and food insecurity can be a critical barrier to effective care of HIV-positive individuals.

Malabsorption

Malabsorption of nutrients is common in HIV-positive individuals and often can become severe. The gastrointestinal (GI) tract is vulnerable to damage due to the opportunistic pathogens associated with HIV infection.[72] Damage can affect the entire GI tract from the mouth to the anus, resulting in nutrient malabsorption, eating difficulties, and wasting.[72,73] Epithelial cells in the small intestine are necessary for nutrient absorption, however, due to the decrease in the mucosal surface area, malabsorption is common in HIV-positive individuals and often leads to malnutrition.[72-74] Abnormalities in GI function were reported in 88% of participants in the Nutrition for Healthy Living (NFHL) Study.[20] The changes to the intestinal lining of the GI tract caused by HIV have been associated with the malabsorption of fat, leading to the malabsorption of fat-soluble vitamins and a decrease in energy intake.[20,74] Malabsorption of nutrients leads to malnutrition, resulting in weight loss. Other GI causes of malabsorption in HIV-positive individuals include diarrhea, nausea or vomiting.[20,72]

Metabolic changes

Metabolic changes commonly seen in HIV-positive individuals include those that promote protein catabolism and changes in fatty acid metabolism. Metabolic changes often lead to increased macro- and micronutrients requirements.[8] Energy needs vary at different stages of the disease; REE, the rate of consumption of energy by the body while at rest, was about 9-11% increased in untreated HIV-positive individuals.[19,75,76] Furthermore, those with an AIDS diagnosis have greater increases in REE ranging from 25-29%.[19] Even during times of malnutrition REE increases ranging from 14% to 68% in HIV-positive individuals.[77] Associations were identified between REE and fat-free mass

(FFM), with energy expenditure being greater per kilogram of FFM.[78] HIV-positive individuals at a higher risk for increased metabolic demands include those with active infections, fevers or night sweats.[19] Illicit drug usage and some prescribed drugs were also linked to increased metabolic needs in HIV-positive individuals.[79] Other metabolic changes associated with HIV include alterations in fatty acid metabolism and protein catabolism.[8]

Diet Quality

The Healthy Eating Index (HEI) is used to measure diet quality and to evaluate compliance with the USDA Dietary Guidelines for Americans. A high score on the Healthy Eating Index-2010 reflects inclusion of foods such as greens and beans, plant protein, seafood and linoleic and linolenic fatty acids. The HEI also includes a moderation category that emphasizes the reduction of consumption of saturated fats, refined grains, sodium, empty calories and calories from solid fats, alcoholic beverages and added sugars.[80] However, the HEI has not frequently been utilized in the HIV population. When used to determine diet quality of HIV-positive individuals living in Brazil, it was determined that 64% had inadequate dietary quality.[81] While only 23% had a diet classified as healthy, having an average HEI score of 68.3 out of 100.[81] This study also found a correlation between low HEI scores, indicating poor diet quality and obesity.[81] About half (51.7%) of participants were overweight or obese. Furthermore, obesity was positively associated with being a woman, living alone, watching television for 3 or more hours per day, history of dieting, and being from the northeastern or southern United States.[81] The HEI score was 56.2, reflecting a diet of lower-quality and needing

improvement. However, limited data is available on the HEI of HIV-positive individuals living in the United States.

The Alternative Healthy Eating Index (AHEI) was developed by the Harvard School of Public Health as an alternative to the HEI. The AHEI was constructed based on foods and nutrients associated with risk of chronic disease, incorporating research-based scientific evidence on diet and health.[82] The total score is summed based on the following nine components: vegetables, fruits, cereal fiber, nuts and soy, ratio of white meat to red meat, trans fat, the ratio of polyunsaturated fatty acids to saturated fatty acids, duration of multivitamin usage, and moderate alcohol consumption. All nine components are summed up to provide an overall AHEI score that could range from 2.5 to 87.5. Each component contributes between 0-10 points, with the exception of the vitamin component that provides either 2.5 or 7.5 points. High AHEI scores were associated with a 19% lower risk of major chronic disease, 31% of reduced risk of coronary heart disease (CHD) and 33% lower risk of diabetes.[82] Individuals with the highest AHEI-scores had 25% lower risk of all-cause mortality and 40% lower risk of cardiovascular disease (CVD) mortality.[83] A decreased risk of CVD has been observed with consumption of nuts and soy and moderate alcohol consumption.[83]

The AHEI, is twice as strong as the HEI at predicting risk of chronic disease, was designed with Mediterranean dietary influences, with notable differences between the HEI and AHEI in food group and fat quality (e.g. meat sources, whole grains).[84] A comparison of the HEI-2005 and AHEI-2010 showed that both indexes were strongly associated with risk of chronic disease, such as CVD and diabetes.[82] However, the AHEI-2010 had a stronger association with coronary artery disease and diabetes

compared to the HEI-2005.[82] Campa et al.[85] reported that the AHEI was significantly associated with viral load, and with parameters of nutritional status and dietary intake such as body cell mass, serum albumin, hemoglobin, iron intake, and adequate caloric intake.

Adequacy of dietary intake is an important issue when treating HIV-positive individuals. Analysis of dietary intake is necessary to determine if HIV-positive individuals are meeting their Recommended Daily Allowances (RDA) and to identify where deficiencies exist. Studies reporting the dietary intake of HIV-positive individuals living in the United States are limited. Luder et al.[12] used 3-day dietary intake records to evaluate dietary intake of HIV-positive individuals living in New York City. The average dietary intake of energy was 74% of the RDA, with fat contributing 34%.[12] While 84% of those surveyed reported vitamin and mineral supplemental use, nutrient intake was below 90% of the RDA for vitamin B-6, magnesium, zinc, and copper.[12] Inadequate intake was reported in most cases, HIV-positive individuals who reported the consumption of three meals a day, were consuming less than 90% of the RDA for micronutrient intakes.[86] Protein intake was reported at 41.65 grams below the RDA for males and 39.23 grams below for females.[7] Respondents reported consumption of a variety of foods, but deficiencies in iron, calcium, vitamins A, C, niacin and riboflavin were noted.[86]

Participants also reported excessive intakes of total fat and cholesterol due to the increased consumption of meat and eggs.[81] Hendricks et al.[87] identified 3 distinct dietary patterns among HIV-infected adults: fast food and fruit drinks, juice and soda, and fruit, vegetables, and low-fat dairy in the NFHL cohort. Individuals in the juice and soda

cluster reported the highest caloric intake, which was 12% greater than the National Health and Nutrition Examination Survey (NHANES) average, with higher intakes of sucrose per kilogram of body weight.[87] Individuals in the fast food and fruit drink group were non-white, reported food insecurity with an income meeting the federal poverty level and were exposed to HIV through intravenous drug usage (IDU) or heterosexual contact.[87]

Nutrition Counseling

Nutritional counseling and dietary therapy was recognized for its significant role in the clinical care of HIV-positive individuals. The impact that counseling and therapy have on an individual depends on the type and duration of counseling and the nutritional status of the individual. Health promotion programs aimed at changing dietary behaviors at the individual level are more likely to be successful in improving nutritional outcomes if they also consider the social, cultural, and environmental context in which the behaviors occur.[88] Nutrition counseling for individuals with HIV is vital for the prevention of malnutrition.[89] Registered Dietitians (RD) conduct nutrition assessments in order to provide nutrition care plans that are personalized to meet the particular needs of the individual. The nutrition care plan of HIV-positive individuals needs to be tailored to their particular stage of the disease while taking into account any comorbidities that might exist.[89]

There is a lack of evidence on whether brief nutrition education can succeed in improving long-term dietary intake. The SMART/EST trial investigated the impact of nutrition counseling on dietary intake in HIV-infected individuals living in New York City and Miami, Florida.[32] HIV-positive women attended training that consisted of

coping skills, stress management and nutrition education that was provided either in a group setting or individually.[32] While gearing the study towards disadvantaged individuals, it was limited to female participants and excluded individuals who were illicit drug users. Group nutrition education meetings that utilized predesigned materials did not allow the tailoring of sessions to individualized needs. However, results from the Rapid Eating Assessment showed that with only two group meetings, improvements were seen in fat and sugar consumption and continued at least 18-months after the intervention.[32]

Nutrition intervention studies conducted in other countries have shown positive associations with dietary outcomes. In Africa, Tabi et al.[88] showed that nutritional counseling was effective in improving health outcomes for malnourished individuals who were not on antiretroviral therapy (ART). With the promotion of dietary increases in protein intake, underweight participants were encouraged to gain weight.[88] On average, females gained 2.71 kilograms while males gained 3.36 kilograms over a 7-month timeframe.[88] Nutritional counseling programs with RD's can also prove useful in preventing dyslipidemia for HIV-positive individuals initiating medication therapy. Quarterly nutritional guidance with an RD improved dietary fat intake with reductions seen in fat intake and triglyceride levels.[46] A study in Brazil conducted by Lazzaretti et al.[46] showed that individualized nutrition counseling improved dietary intake by decreasing daily calories, cholesterol and percentage of dietary fat. Nutritional plans, based on dietary needs, current economic status, and food preference, led to an increase in carbohydrate and dietary fiber intake compared to those without dietary intervention.[46] At the conclusion of the 1-year nutrition intervention study, participants decreased their

total caloric and fat intake, which resulted in an improvement in lipid profiles for dyslipidemia in the intervention group.[46] Individualized nutrition counseling for 1-year improved dietary intake by decreasing total fat intake and increasing fiber intake.[90] Dietary improvements seen in this group correlated with a significant improvement in LDL-cholesterol levels and moderate improvements in fasting glucose levels and diastolic blood pressure.[90]

Substance Abuse

Substance abuse has been a major public health concern in the HIV community since the beginning of the epidemic. Coupled with HIV-infection, substance abuse further compromises nutritional status.[91-93] An estimated 3 million HIV-positive individuals have reported substance use.[94,95] Substance abuse hastens HIV disease progression and negatively impacts treatment adherence.[94-96] Alcohol abuse, for example, is associated with non-adherence to HIV-treatment, which in turn is associated with inadequate viral suppression and the development of resistance to ART.[97] It is estimated that only 4% of HIV-positive IDU's receive ART.[94] Substance abuse and addiction are also associated with other chronic infectious diseases, including hepatitis B and C, and tuberculosis.[98] Effective treatment for these chronic conditions can be very challenging in HIV-positive individuals who continue to use these substances.[98] Untreated illicit drug abuse has a negative impact on access to HIV-related treatment and care and HIV outcomes, such as disease progression.[96,98,99]

Currently, exploration of the relationship between substance abuse and dietary counseling in HIV-infected individuals is limited, but it is known that the risk of malnutrition in the HIV population is greater amongst substance abusers.[91] Use of

cocaine and other opiates has been associated with weight loss.[79,100] Furthermore, drug abuse is related to wasting and signs of protein-energy deficiency.[79]

The consumption of alcohol is highly prevalent in the HIV community, with beer being the most commonly consumed.[101] HIV-positive individuals who consume more than 2 alcoholic drinks a day are at an increased risk of suffering from malnutrition.[92] Correspondingly, the likelihood of malnutrition was associated with lower BMI, irregular eating habits, and inadequate dietary intake.[92] Thirty-three percent of those who consumed excess alcohol had BMI under 18.5 kg/m^2 versus 5.7% alcoholics who were obese.[92] Furthermore, the consumption of 2 or more drinks a day almost tripled the risk of a reduced CD4 cell count and increased viral load in individuals on ART.[101] When combined with crack-cocaine CD4 cell counts were further compromised and disease progression was hastened.[101] Those who consumed excess alcohol were more likely to report lack of attention to nutrition labels and reported skipping meals to purchase alcohol.[102] Twenty-nine percent of participants reported not having enough food to eat 30 days prior to the interview.[102] Furthermore, drinking severity was significantly related to memory loss, stomach issues, weight concerns, kidney disease, and diabetes.[102]

A comparison of BMI between HIV-positive cocaine users versus HIV-positive non-users showed that the BMI in cocaine users was 1.4 kg/m^2 less than those who did not use drugs.[91] Drug users with HIV reported inadequate dietary intakes, lower intakes of dietary fat, and a decreased total energy intake.[93] Fifty-two percent of the HIV-positive drug users had BMI lower than 18.4 kg/m^2, which is defined as being underweight.[93] Also, dietary intake of HIV-positive drug users indicated a higher dietary protein and fat intake when compared to HIV-negative drug users.[103] Sixty-one percent of

the HIV-positive drug users reported consuming two or fewer meals per day with the inadequate intake of vegetables, fruit, and milk products.[103] The risk of malnutrition in HIV-positive substance users indicated that dietary counseling may be beneficial to this vulnerable population.[91]

Often when addressing substance abuse, other concerns are uncovered that need to be addressed. A study monitoring the impact of ancillary services for the treatment of substance abuse showed an association between treatment and increased entry into primary care and clinic retention improved for HIV-positive individuals.[104] Furthermore, individuals with a substance abuse problem were twice as likely to remain in medical care if they also participated in a self-help group.[105] In addition, HIV-positive individuals who utilized ancillary services were more likely to attend regular follow-up appointments with primary care doctors.[106] Common ancillary services utilized include case management, mental health care, drug assistance, housing and food and nutrition services.[106] When provided to individuals who were not HIV-positive, nutrition counseling was positively related to substance abuse outcomes during drug addiction treatment.[107] Comparable results were found in a group of alcohol-dependent individuals. Six months after receiving nutrition counseling during an inpatient rehabilitation stay 80% of respondents reported continued abstinence from alcohol consumption.[108]

Barriers to Nutritional and Health Interventions

HIV requires long-term treatment and daily self-management. Self-management is pivotal for the care of HIV-positive individuals to delay disease progression. For better health outcomes, HIV-positive individuals should be advised regarding their dietary

intake. HIV-positive individuals need dietary recommendations that are supported by scientific evidence, are easily understood and can be used in everyday life. The importance of dietary counseling for HIV-positive individuals has influenced programs such as the Ryan White Foundation and The Magic Johnson Foundation to include nutritional services as part of auxiliary programs. However, these services are underutilized. For example, a study in Boston showed that only 9.6% of the sample surveyed received nutritional services in the previous 12-months, furthermore only 18.1% of the sample was indicated at a "need" for nutritional services.[106] Information regarding the barriers that prevent the attendance of dietary counseling sessions with an RD is limited. In a small scale study Brunner et al.[109] reported the common barriers to the attendance of nutritional services were concern about confidentiality and difficulty in keeping appointments. Less commonly reported barriers were the cost of attendance, multiple locations for services, forgetfulness and interference with a new job.[109] However, these barriers did not deter individuals from referring others to the nutrition program, participants felt the benefits of nutrition awareness on disease progression and general health was vital for the HIV-positive community.[109]

HIV-positive individuals face multiple barriers to general healthcare, therefore, experience unmet medical and ancillary service needs.[110] Various factors influence adherence to treatment in HIV-positive individuals. The poverty level of the neighborhood is strongly associated with HIV-related outcomes. The higher the poverty level and unemployment rates of the area, the poorer the HIV-related health outcomes are and less adherence to ART.[111] Other barriers to medication adherence include forgetfulness, being away from home, difficulty of regimens, side effects of medication

and lack of knowledge.[112-114] Some common barriers to receiving health care in this population include lower literacy, education levels, and lack of transportation.[115,116] The utilization of multiple transportation services and using new technology for frequent messaging have been shown to improve adherence and retention with ancillary services.[114,117] Furthermore, individuals who received needed ancillary services were more likely to follow-up with the medical doctor on a routine basis.[110] In addition, food insecurity has been identified as a barrier to both accessing health care and to medication adherence.[118] Some identified barriers that respondents listed can potentially be overcome with better education regarding HIV-related care and regimens.[112,119]

The ability to comprehend nutritional recommendations will affect compliance with dietary changes and has been shown to decrease with age.[120] Furthermore, individuals lacking information regarding the relationship between dietary intake and disease progression avoided nutritious options.[121] In a study conducted by Bukusuba et al.[122] 89.5% of the participants reported receiving nutrition education, however, only 51.9% could identify what a nutritious meal was. Other identified social barriers that affect nutritional status include lack of a caregiver, transportation, assistance with shopping for food, preparation of food and physical weakness.[121] Disadvantaged women with HIV may experience considerable barriers to dietary changes. When compared to men, they have higher rates of depression, leading to greater psychosocial stress and emotional eating.[123] Another identified barrier is that primary care physicians hesitate to refer clients to RD's. An example of this is a survey of Primary Care Physicians revealing that only 36.6% are referring patients for dietary counseling outside of their

practice.[124] Information regarding the rate of referrals for nutritional counseling within the HIV population is not available.

Literature Review Summary

The nutritional problems seen in the HIV population are significant and contribute to comorbidities and mortality.[27,46] With access to a variety of therapies, including ART, individuals are able to live longer with HIV. However, nutritional and metabolic complications associated with the HIV therapy such as lipodystrophy, dyslipidemia, weight gain and other metabolic derangements are becoming a major concern.[44,46] There are many ways that HIV can affect nutritional intake and status; therefore, nutrition counseling from an RD is an essential component of HIV treatment.[89] Early dietary intervention can decrease nutrition-related problems that are often seen in the HIV population. However, regardless of the stage of illness, Medical Nutrition Therapy needs to be individualized and prioritized as an integral part of the patient's total care.[89]

Dietary interventions are beneficial for HIV treatment and could improve optimal health outcomes associated with disease progression.[32,88,101] Interventions should not be limited to nutritional counseling but should also include information to improve food security.[125] The primary objective of nutrition counseling in individuals with HIV is to provide sufficient amounts of nutrients either from diet or supplements as needed that will help improve nutritional status and improve outcomes associated with HIV disease progression. However, studies investigating the impact of nutritional services on the dietary intake and nutritional outcomes in HIV-positive individuals are lacking. This study determined the barriers to participation, and the impact of nutritional services on dietary intake, nutritional status, and disease progression in HIV-positive individuals.

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CHAPTER III: METHODS

Design

The study was a cross-sectional study that included a secondary analysis of variables collected by the Miami Adult Studies on HIV (MASH) cohort which included a total of 803 HIV positive and 78 uninfected participants followed from 2002 to 2014. This study collected data from February to April of 2014. One hundred and thirty people living with HIV (PLWH) on stable antiretroviral therapy (ART) were consecutively recruited in a convenience sample from the participants who were already enrolled in the MASH cohort. In addition, thirteen health professional, who were serving PLWH were also consented and surveyed on their attitudes and beliefs on referring them to a Registered Dietitian (RD) for nutrition counseling.

This study was approved by the Florida International University Institutional Review Board. Consent forms were developed for both PLWH and health professionals. The initial screening included a detailed explanation of the current study, as well as obtaining informed, voluntary written consent for participation.

Twelve health professionals were enrolled to respond the Health Professional Survey. To obtain a study sample of 130 PLWH, a total of 150 patients were screened. Outreach personnel from the MASH cohort collaborated in scheduling of appointments and establishing contacts with the participants. Data collected from the PLWH surveys were used to divide participants for the analyses into those seen by an RD in the last 12 months and those who were not consulted by an RD. The data collected during the visits were used for descriptive and inferential statistics.

The MASH Cohort

At the time of the recruitment from MASH, there were two active NIH-sponsored studies for which more than 800 PLWH were enrolled. These two studies were 'HIV and HIV/HCV co-infection, Disease Progression, Oxidative Stress and Antioxidants' also known as the "**Co-infection study"** and 'Alcohol & Antiretrovirals in HIV infection, Oxidative Stress and Liver Disease' also known as the "**Alcohol study**." The Co-infection study looked for the adverse effects of HIV/HCV co-infection on oxidative stress and plasma levels of antioxidant micronutrients and the net effects of these variables on HIV disease progression. The "Alcohol study" similarly examined the effects of alcohol consumption on oxidative stress, mitochondrial DNA damage and hepatocellular injury, and their combined effects on HIV disease progression. Participants were interviewed every three months at the Borinquen Health Center, and at the semiannual and annual visits blood and urine were collected for laboratory values. Both the studies had stringent eligibility criteria, meticulous recruitment, retention protocols and safety and confidentiality procedures.

Characteristics of the MASH cohort

For the two NIH grant sponsored studies, the "co-infection study" and "alcohol study," a total of 803 HIV positive and 78 uninfected participants were followed from 2002 to 2014, for a period of twelve years. This constituted the Miami Adult Studies on HIV (MASH) cohort and included a specimen repository and database for a number of clinical, laboratory, socio-demographic, substance abuse and behavioral data collected at regular intervals during the studies. The mean age of the cohort was 45.1 ± 7.9 years. Of these participants, 74.7% were African-American, 6.8% were non-Hispanic Whites,

19.9% were Hispanics, and 1.6% belonged to other races. Men constituted two-thirds of all participants. The mean family income was $439 ± 638.4 per month. The average time from diagnosis of HIV was 12.2 ± 8.7 years. About 33.6% reported adequate viral control represented by undetectable (< 75 copies/mL) HIV viral loads while 23.4% were in advanced HIV disease represented by CD4 counts less than 200 cells/μL. About 54.4% of the cohort reported some form of illicit drug use. The mean CD4 cell count for the entire cohort was 470.8 ± 444.8 cells/μL. The mean HIV viral load was 3.2 ± 1.3 $\log_{10}$ copies/mL of HIV viral RNA.

Inclusion Criteria for Co-infection study (obtained from the original grant)

1) HIV/HCV co-infected, or HIV mono-infected participants with HBV infection ruled out and documented in the medical chart. HIV mono-infected participants will have qualitative HCV-RNA analysis by PCR to rule out HCV infection also documented in the medical chart
2) Identified from the Borinquen Healthcare Center
3) HIV/HCV co-infected patients determined with biopsy or another accepted non-invasive method of staging to be either F0-F5 fibrosis grading or its equivalence
4) Age 40-60 years
5) BMI >18, but < 40 kg/m2
6) Compliant, as determined by regular visits to the clinic and adherence to treatment
7) Free of significant active psychiatric conditions
8) Free of co-morbid diseases (uncontrolled diabetes, symptomatic cardiovascular disease)

9) Willingness to provide consent for a second biopsy if clinically indicated
10) Signature on a consent form
11) Willingness to participate in a study for 4 years (monthly contact with the clinic for follow-up, assessment visits at baseline and every 3 months thereafter for 48 months)
12) English speaking

Exclusion Criteria for Co-infection study

1) HBV infection
2) BMI <18, or > 40 kg/m2
3) Chronic inflammatory diseases
4) Age<40, or >60 years
5) Elevated liver enzymes > than grade 2 according to ATCG criteria, in HIV mono-infected participants
6) Ishak score F6 or end-stage liver disease defined by clinical criteria of hepatic encephalopathy, esophageal varices, ascites, or hepatocellular carcinoma
7) Receiving HCV treatment
8) Pregnancy or the intent to become pregnant. Although the proposed study is observational, CD4 cell count increases in pregnancy, and pregnant women need to be referred to the obstetrics clinics where they are given micronutrient supplementation, which may confound the micronutrient and the oxidative stress findings

Inclusion Criteria for Alcohol Study (obtained from the original grant)

- HIV status documented in the medical chart

- HIV-positive adults identified from the Borinquen clinics where the participants are followed medically, and we will have access to their medical charts with written permission of the participant
- ART naïve or treatment experienced
- For Groups 1 and 2, CD4 cell count < 350, initiating ART and achieving undetectable HIV viral load within 6 months, just prior to baseline. The ART will be a tenofovir based regimen
- For Groups 3 and 4 (CD4 cell count > 450, and viral load < 50,000), not yet eligible for ART
- For Group 5 (85 HIV-negative participants) participants will have a documented seronegative test in the last year
- Willing to respond to questionnaires on alcohol use pattern, frequency and type of beverages consumed
- Age 18 – 60 years old
- BMI >18, but < 40 kg/m2 to control for malnutrition or obesity
- Compliant, as determined by regular visits to the clinic and adherence to treatment
- Controlled co-morbid diseases (diabetes, symptomatic cardiovascular disease, hyperlipidemia, and metabolic syndrome). Free of HBV and HCV (as confirmed by test results)
- Free of heavy tobacco smoking (defined as > 20 cigarettes/day)
- Signature on a consent form

- Willingness to participate in a study for 2 years (monthly contact with the clinic for follow-up, assessment visits at baseline and every 3 months thereafter)

Exclusion Criteria for Alcohol Study

- HBV and HCV infected as confirmed by testing or medical records
- BMI <18, or > 40 kg/m2
- Chronic inflammatory diseases
- Pregnancy or the intent to become pregnant. Although the proposed study is observational, CD4 cell count increases in pregnancy. Pregnant women will be referred to the obstetrics clinics.

Inclusion/Exclusion Criteria for the current study.

In addition to the eligibility criteria for the MASH cohort for PLWH, this study had its own selection criteria for PLWH and for the participating health professionals:

1. ***Inclusion/Exclusion Criteria for people living with HIV***:

Inclusion Criteria:

- Enrolled in the MASH cohort
- History of stable ART
- Willing to participate in a study that required approximately one hour for answering questions regarding nutritional counseling

Exclusion Criteria for the Analysis of Association between consulting an RD in the last 12 months and Cardiovascular Risk:

- Not having documentation for lipid profile in the medical documentation.
- Conditions that made interview the individual difficult.

2. *Inclusion Criteria for Health Professionals:*

- Health Professionals (Physicians, Nurses and Case Managers) working currently with PLWH.

Recruitment of PLWH as Study Subjects

PLWH were recruited from the MASH cohort followed at the FIU-Borinquen Research Clinic. Participants were a consecutive convenience sample of 130 PLWH. We recruited participants from both genders and major racial and ethnic characteristics. To ensure compliance with the current study, the participants were provided incentives such as reimbursement for their time and effort ($5.00) and information on the importance of having professional nutritional counseling.

Initial Screening and enrollment

During the screening, PWLH and health professionals were explained the details of the study and the eligibility criteria; if they were eligible and willing to participate, they were consented and enrolled in the study. The participants were also assured confidentiality of the data obtained from them, as well as voluntary withdrawal from the study without any penalization.

Safety of Human Subjects

According to the eligibility criteria of the MASH cohort, PLWH recruited for the current study were under standard medical care. To reduce the risk of loss of confidentiality about the participant's medical condition, the data collected were entered into a de-identified database and separated from the consent forms, which were the only document that linked the participants to the study. Data for this study was password protected to ensure safety and confidentiality. Hard copies of the consent form were kept

in a locked cabinet in the office of the Major Professor, Dr. Adriana Campa, and only accessible to investigators for audit purposes.

Pilot Testing of the questionnaires, logistics, and instruments

Though all the questionnaires and instruments used in the current study were already validated in original studies and publications, we additionally pilot tested all questionnaires and instruments in a subset of 15 participants to assess the understanding of the questions by the participants. We evaluated the wording, understandability and schematic and grammatical layout of the administered questionnaires and develop an efficient clinic logistic to administer them. No changes to the questionnaires and logistics were made throughout the duration of the study.

Study Visit

All eligible participants were screened and enrolled into the study and the study visit followed the screening or were scheduled at their earliest convenience, including the dates when the participants were screened for their MASH visits. The study visits for PLWH and healthcare professionals included completion of the *Barriers to Nutritional Counseling* survey.

At the end of the study visit, we ensured that the data collected did not include any personal identifiers and were transported safely to a secure storage location within the premises of Florida International University ensuring their confidentiality.

Safety monitoring of PLWH

The majority of the safety monitoring procedures for PLWH were already in place in the MASH cohort when we collected data for the current study. The MASH cohort obtained viral loads and CD4 counts from medical records with the participants written

permission. Though there were no adverse events recorded during the current study, as this was not an intervention study, all protocols were in place for prompt intervention and resolution of adverse events. In case of adverse events severe enough to warrant prompt medical attention, the MASH studies had provisions for referrals to the nearby hospitals and emergency services. The MASH cohort was already monitored for signs of medical illness during follow-up visits.

Outcomes and assessments

Several variables such as age, gender, race/ethnicity, education, income, smoking, alcohol consumption, drug use, ART medications, CD4 counts, plasma viral load, 24-hour dietary intakes, anthropometrics, body mass index (BMI), total fat mass, lipid profiles, vitals, and food security questionnaire (FSQ) scores were in the data repository of the MASH cohort and were used in the statistical analyses of the current study. The following tables provide a brief description of variables collected during the study (Table 1) as well as variables transcribed from the MASH cohort (Table 2).

Barriers to Nutritional Counseling Surveys

The two types of surveys used for this study were a modification of those used by Brunner et al.[1] and Hatsu et al.[2] Questions relevant to our study were combined to form two separate surveys, which were used to determine perceived barriers to receiving nutritional services.

- The first survey developed was the ***Barriers to Nutritional Counseling Survey for PLWH***, which was used to probe information regarding the use of nutritional services. The first part of the survey sought to capture information about trusted sources of nutrition information and gathered information about nutritional

services, including topics of nutrition education that participants were interested in learning about. The second part of the survey was designed to identify the barriers preventing participants from seeing an RD, along with those that interfere with dietary advice and intake.

- The second survey was the ***Barriers to Nutritional Counseling Survey for Health Professionals,*** which was used for healthcare professionals and ancillary personnel to identify barriers that professionals face when referring patients to an RD. The first part of the survey asked general questions regarding their role in nutritional services and counseling, while the second part was designed to identify specific barriers preventing the referrals of patients to an RD and left room for additional comments about barriers their patients face.

Demographic and Socioeconomic information

The MASH cohort collected demographic and socioeconomic information for participants living with HIV. Information used for the present study included age, gender, race/ethnicity, education and income levels. A number of health and lifestyle related factors like tobacco use, alcohol consumption, drug use and types of antiretroviral medications were also collected from the MASH data repository.

24-hour dietary recall

MASH personnel were trained to obtain 24-hour dietary recalls, which were used to estimate participants' dietary and nutrient consumption. During each MASH visit, participants were queried about foods and beverages consumed on the day prior to the visit. All details including cooking methods, amount consumed, additional ingredients and seasonings and food brands were recorded to ensure the comprehensiveness of the

obtained information. We also used props like food models and measuring cups to ensure accuracy of the amounts and volumes recalled as well as providing cues for better recall of consumed foods. We used Nutribase Professional Software Version 9 (Cybersoft Inc, 2011), into which all the collected information were entered to obtain an estimation of several nutrients consumed by the participants. The average of two 24-hour dietary recalls was used to assess diet intake and diet quality. Outcome variables extracted from Nutribase included calorie consumption, total fat, saturated fat, total carbohydrates, protein, and total fiber.

Alternate Healthy Eating Index (AHEI)

Dietary intake outcomes were then used to calculate the AHEI score using the method from McCullough et al.[3] The AHEI score is based on the following nine components: vegetables, fruits, nuts and soy, ratio of white meat to red meat, cereal fiber, *trans* fat, the ratio of polyunsaturated fatty acids to saturated fatty acids, duration of multivitamin usage, and moderate alcohol consumption. All nine components were summed up to provide an overall AHEI score which could range from 2.5 to 87.5.[3] Each component has a criterion to achieve a score between 0-10 points, with the exception of the vitamin component which provided either 2.5 or 7.5 points.[3] A score of 10 indicates that the recommendations for that component were met, while a zero indicates no servings consumed for that group.[3] Refer to Table 3 for further information on the scoring criteria.

Food security questionnaire

Food security status was determined using the US Household Food Security Survey Module, which measured food availability, access, and sufficiency over a 12

months period.[4] Following standard procedures, responses were coded, and food security scores were calculated. This was used to classify patients into following categories:

- For scores of 0-1: high/marginal food security – little or no indication of limitation with food access or changes in diet quality and food intake;
- For scores of 2-4: low food security- reports of reduction in diet quality, with little or indication for reduction in food intake;
- For scores of 5-6: very low food security- Several indications of disruptions with eating patterns reported, in addition to reduction in food intake.

Physical Examination and Bio-impedance analysis (BIA)

In the MASH, height was recorded using a stadiometer, calibrated according to the instruction manual. **Height** was recorded to the nearest 0.5 inch after removing shoes, socks, and other footwear. Height was recorded only once to ensure that it was uniform, and there were no minor variations during every successive visit. **Weight** was measured every visit for the MASH visits, to the nearest 0.1 lbs. using a standard weighing machine which was calibrated and maintained throughout the study and the participants were requested to remove, their watches, shoes, mobile phones or other heavy materials possessed by them. The data so obtained along with age were entered into the **bio-impedance machine, Biodynamics-450,**[5] to obtain several body composition measures such as, body cell mass, extracellular mass, lean body mass (LBM), fat mass, body mass index (BMI) and intracellular and extracellular fluid levels. In addition, we also obtained the **waist-to-hip ratio** using a non-stretchable tape to

measure the waist and hip circumference at the narrowest levels of the waist and widest levels of the hip.

CD4 Counts and Viral Load

The Borinquen provides a variety of comprehensive health services for HIV/AIDS patient, which include quarterly check-up visits, laboratory services, nutritional counseling and emergency services. Based on requests from their primary health care physicians or their HIV/ STD consultant at Borinquen, CD4 counts, viral loads and other clinical variables are measured every six months for all HIV-infected patients. The MASH data repository collected and documented these reports after appropriate medical release forms were signed by the participants. The MASH cohort participants were paid a compensation of $15 every six months to motivate them to provide timely submission of medical records and lab reports, which included CD4 counts and viral load. The CD4 counts and viral loads were analyzed as both continuous and categorical variables. In analyses where CD4 counts and viral load were used as continuous variables, they were transformed into CD4 square root and $\log_{10}$ viral load to ensure normal distribution and better model fit criteria. In analysis where CD4 counts and viral loads were used as categorical variables both the variables were divided into 3 groups of adequate control on disease progression (CD4 count > 500 and viral load < 75 copies of HIV RNA); moderate control over disease progression (CD4 count between 200-499 and viral load between 76-9999 copies of HIV RNA); and inadequate control over disease progression (CD4 count < 200 and viral load > 10,000 copies of HIV RNA), based on immunological and virologic stratification of HIV disease progression by the World Health Organization (WHO).[6,7]

Biochemical data and Laboratory Values

Fasting blood samples were drawn for the assessment of hemoglobin, hematocrit, albumin, fasting glucose, zinc, and selenium. Blood samples were analyzed by a commercial laboratory for levels of hemoglobin, hematocrit, and albumin. Levels of zinc and selenium were processed at Dr. Baum's Nutrition Research Laboratory at Florida International University.

Alcohol, tobacco, and illicit drugs

A trained interviewer administered alcohol, tobacco, and drug abuse questionnaires. The alcohol use questionnaires include information on frequency and type of alcohol consumption over time collected by the Lifetime Alcohol History (LAH),[8,9] and history of alcohol binging and prolonged heavy exposure utilizing the validated and standardized Alcohol Use Disorders Identification Test (AUDIT).[8,9] Scores provided from the AUDIT questionnaire were used to determine misuse of alcohol. Scores equal or higher than 8 indicate harmful or hazardous drinking tendencies. Scores indicative of alcohol dependency are gender dependent; for women dependency is classified as having a score of 13 or more and for men the score is 15 or more.

A well-validated drug use questionnaire from previous studies[10,11] was administered verbally. This questionnaire detailed the type, frequency, and mode of administration, of illicit drugs and tobacco in the previous 6 months. At the same visit, urine samples were taken and analyzed for evidence of drug abuse using urine toxicology kits (American Bio Medica Corp. Kinderhook, NY) for the presence of barbiturates, benzodiazepines, cannabinoids, hallucinogens, morphine, and amphetamines.

Data collection for the study

To reduce observer bias, we used standardized procedures with uniform protocols. All equipment, questionnaires, and instruments were calibrated according to the instructions in user's manual and the requirements of the MASH cohort. We also assured that these procedures were done prior to the start of the study to reduce wait time, as well as the time taken to administer the questionnaires and assessments. Each visit lasted approximately 60 minutes and was primarily devoted towards answering and filling out the forms and questionnaires. Participant responses were recorded and maintained in a paper-based research charts. Every chart included a checklist of activities, and the questionnaires were arranged according to the specific aims of the current study. The consent forms were maintained in a locked cabinet in the office of Dr. Adriana Campa, separately from the study charts, which were identified only by an ID number to ensure confidentiality of the data collected. All the research charts were quality assured at least twice during the course of the study to avoid missing data and non-rectifiable errors.

Sample Size Calculation

G-Power is a common software used for power analysis in social and behavioral research. G-Power 3.1[12] provides calculations for determining effect size and graphic options. The software allows for several types of power analysis with adjustments according to the study designs and sample size limitations.[12] Hypothesis 2A was used for calculating the sample size for the study. The input parameters for the sample size calculations included a two-tailed t-tests to determine the difference between two independent means or two group means. The effect size was set at 0.5. Cohen et al.,[13] has described three effect sizes: 0.3 for weak associations, 0.5 for moderate associations, and 0.8 for strong associations. We set the probability of alpha error at

0.05 and statistical power levels at 0.80 i.e. 80 percentage. We obtained an actual power of 0.801 for a total sample size of 128 participants for the study. We rounded this figure to 130 participants for the study.

Statistical methods used in the study

SPSS-22 for windows was used for analyzing the relationship between nutritional counseling and outcome variables in the study. Standard statistical methods were used to calculate the rates, describe the demographic characteristics and show basic summary statistics. T-tests and chi-square tests were used to test significant differences between the two groups, the participants that have seen the RD in the last 12 months and the group of participants who did not. Spearman rank correlations was used to estimate the associations between identified barriers and several categorical outcome variables that affected the dependent variable. Linear regression models were used to compare the beta (β) between the two groups. Models were adjusted for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes. Metabolic Syndrome (MetS) was examined in relation to standard and other risk factors. The results were considered significant for $P < 0.05$.

Quality control

Several steps were taken to ensure that data collected during the study were accurate and free from errors. All the procedures were done according to the 'Good Clinical Practice' protocols for quality control. We strived to ensure that there was no breach of protocol, and we had adequate procedures to resolve them and take effective measures if we found any such occurrences. The Doctoral Candidates responsibilities included contacting participants, consenting them, monitoring every visit and ensure that

the forms were complete before the participant left and entering data into the software programs. MASH staff members also collaborated in quality assurance procedures. The PI, Dr. Marianna Baum, Ph.D., and the committee members were constantly consulted to discuss logistic and supply issues. The gathered data were regularly monitored through standardized procedures to ensure validity as well as reliability. The activities conducted during each week were discussed in weekly meetings to get feedback on the progress of the project as well as technical issues. A weekly review of performance, protocol compliance, and recommendations was conducted by the Major Professor, Dr. Adriana Campa, Ph.D., during the data collection and data entry processes. The security and confidentiality of data were ensured by coding and de-identification procedures. An elaborate system of patient identification numbers and study identification numbers were already in place in the MASH cohort and were used for this project. All the working steps were monitored to ensure adequate quality control. The confidentiality and security of the data were further strengthened by assigning appropriate password protections and accessibility codes for all the software used in the current study.

Table 1: Outcomes and assessments collected during the current study	
Barriers to Nutritional Counseling HIV+ Participants	Nutritional counseling history Desired nutrition-related education Trusted sources of nutrition information Barriers to seeing an RD Barriers to dietary intake
Barriers to Nutritional Counseling Medical/Ancillary Personal	Nutritional counseling information Barriers to referring HIV+ patients

Table 2: Assessment variables collected by the MASH cohort.	
Demographic and socioeconomic	Age Gender Race/Ethnicity Income Education Marital Status
24-hour dietary recall	Calories Protein Carbohydrate Fiber Fat Intake Zinc Vegetable Intake Fruit Intake Meat Intake Nuts & Soy Intake
Anthropometric	BMI Waist-hip ratio
Bio-impedance analysis (BIA)	Fat Mass Fat % BCM BCM %
Alcohol, tobacco, and illicit drugs	Alcohol/Frequency Smoking/Frequency Illicit Drugs/Frequency
Medication history	Medication Regimen Multivitamin Usage
Food Security Questionnaire (FSQ)	Food Security Score Supplemental Nutrition Assistance Program (SNAP)
Biochemical analysis	Hemoglobin Hematocrit Albumin Fasting Glucose Zinc Selenium
Patients' laboratory records	Disease Progression CD4 Cell Count Viral Loads Lipid Profile Total Cholesterol HDL-Cholesterol LDL-Cholesterol Triglycerides

Table 3: Construction of AHEI scores.

Components	Criteria for min. scores	Criteria for max. scores	Possible score range
Vegetable (serving/day)	**0**	**5**	**0-10**
Fruit (serving/day)	**0**	**4**	**0-10**
Nuts and Soy (serving/day)	**0**	**1**	**0-10**
Ratio of white to red meat	**0**	**4**	**0-10**
Total Fiber (% of energy)	**0**	**24**	**0-10**
Trans Fat (% of energy)	**≥ 4**	**≤ 0.5**	**0-10**
Ratio of PUFA to SFA	**≤ 0.4**	**≥ 1**	**0-10**
Duration of multivitamin use	**< 5 years**	**≥ 5 years**	**2.5-7.5**
Alcohol (servings/day)			
Men	**0 or > 3.5**	**1.5-2.5**	**0-10**
Women	**0 or > 2.5**	**0.5-1.5**	**0-10**
Total Score			**2.5-87.5**

Abbreviation: PUFA = Polyunsaturated fatty acids; SAF = Saturated fatty acids.
*Each AHEI component contributed from 0-10 points to the total AHEI score, except the multivitamin component which was dichotomous and contributed either 2.5 points (for nonuse) or 7.5 (for use). A score of 10 indicates that the recommendations were fully met, whereas a score of 0 represents the least healthy dietary behavior. Intermediate intakes were scored proportionately between 0 and 10.

Table 4: Statistical analyses methods for individual hypotheses	
Hypothesis	**Statistical Analyses (Independent variable is caffeine intake)**
Hypothesis 1A Analyses	Barriers were described using means and standard deviation. Student t-tests and chi-square were be used to determine differences in barriers between groups. Spearman rank correlations were used to estimate associations between identified barriers and other categorical outcome variables that affect attendance with an RD.
Hypothesis 1B Analyses	Barriers were described using means and standard deviation.
Hypothesis 2A Analyses	AHEI scores were described using means and standard deviation. Student t-tests were used to determine if nutritional counseling is associated with changes in the AHEI score. Linear regression models were used to compute the beta (β) for comparisons between the two groups. Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.
Hypothesis 2B Analyses	Nutritional status variables were described using means and standard deviation. Student t-tests and chi-square were used to compare differences in the groups related to nutrition counseling. Linear regression models were used to compute the beta (β) for comparisons between the two groups. Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.
Hypothesis 2C Analyses	Laboratory variables were described using means and standard deviations. Student t-test were used to determine if nutritional counseling is associated with differences in laboratory outcomes. Linear regression models were used to compute the beta (β) for comparisons between the two groups. Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.
Hypothesis 2D Analysis	Student t-tests and chi-square were used to determine if nutritional counseling is associated with changes in CD4 cell counts and viral loads. Linear regression models were used to compute the beta (β) for comparisons between the two groups. Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.
Hypothesis 3A Analyses	CVD risk factors were described using means and standard deviations. Student t-tests and chi-square were used to determine if nutritional counseling is associated with differences in MetS between the two groups. Linear regression models were used to compute the beta (β) for comparisons between the two groups. Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.
Hypothesis 3B Analysis	Student t-tests and chi-square will be used to determine if nutritional counseling is associated with differences in CVD risk factors between groups.

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CHAPTER IV: BARRIERS TO NUTRITIONAL COUNSELING BY A REGISTERED DIETITAN FOR PEOPLE LIVING WITH HIV (PLWH)

Abstract

Objective: People living with HIV (PLWH) face multiple barriers to access treatments, experiencing unmet medical and ancillary service needs. The purpose of this study was to determine the barriers that affect adequacy of dietary intake and impede attendance and compliance with nutritional counseling sessions with a Registered Dietitian (RD).

Methods: After consent, a subsample of the Miami Adult Studies on HIV (MASH) cohort consisting of 130 consecutively recruited HIV-positive study participants completed a survey regarding nutritional services, barriers to services and compliance with visits. In addition, healthcare workers that provide services to PLWH, completed a survey to determine barriers preventing these caregivers from making referrals for dietary counseling. Student t-tests and chi-square were used to analyze data on barriers. Spearman rank correlations were used to estimate associations between identified barriers and other categorical outcome variables that affect attendance with an RD.

Results: Of the 130 participants surveyed, 46.2% reported nutritional counseling with an RD in the previous 12-months. Although 75.4% of all participants have seen an RD in the past, more than half of them (53.8%) were not receiving nutritional services. The most trusted sources (68.5%) of nutritional information were equally the Physician and RD. HIV-positive participants were more frequently interested in learning about the following topics: weight concerns (73.1%), shopping healthy (72.3%) and on a budget (70.3%). The most identified barriers to participating were difficulty in keeping appointments (33.8%), location (24.6%) and lack of referral to services (23.8%). Barriers affecting the referrals

to RD's from HIV health professionals included that the patient was not interested, education level, and patient not requesting the services. Barriers that the participants identified towards nutritional counseling were highly correlated with each other.

Conclusions: Our findings suggest that the majority of PLWH in Miami-Dade County have received some nutritional counseling with an RD at some point after HIV diagnosis. The most commonly identified barriers to access nutritional care can be overcome by providing education to healthcare providers and patients, facilitating transportation, and providing locations closer to the places where they are receiving medical treatment to make it more convenient.

Keywords: HIV; barriers to healthcare; nutrition counseling; nutrition education

Introduction

The Academy of Nutrition and Dietetics (AND) recommends that people living with HIV attend nutritional counseling with a Registered Dietitian (RD) on a routine basis.[1] The importance of this dietary counseling recommendation for people living with HIV (PLWH) has influenced programs such as the Ryan White Foundation and The Magic Johnson Foundation to include nutritional services as part of auxiliary programs. However, these services are underutilized as there are multiple barriers that HIV-positive persons face, which interfere with access to healthcare.[2] A survey of Primary Care Physicians revealed that only 36.6% of medical doctors are referring patients for dietary counseling outside of their practice.[3] However, studies determining barriers that prevent the attendance and referrals of dietary counseling sessions of PLWH with an RD are limited. Brunner et al.[4] reported common barriers to attending nutritional services are

concerns about confidentiality and difficulty in keeping appointments. Other less frequently identified barriers included cost, location, forgetfulness and job status.[4]

Barriers to healthcare utilization that have been identified in the HIV population are lower literacy, education levels, housing instability, food insecurity, and transportation.[1,5-7] People living in low socioeconomic neighborhoods face additional barriers to adherence to HIV-related treatments.[8] Schacham et al.[8] found that higher poverty levels and unemployment rates of a neighborhood predict poorer HIV-related health outcomes and adherence to antiretroviral therapy (ART).[8] HIV-positive people face other barriers for adherence to treatment regimens, including forgetfulness, environmental surroundings, difficulty of medical regimens, side effects of medication and lack of knowledge.[9]

Individuals must be able to process and understand the information provided to be able to benefit from the services received. Poor health literacy creates barriers to comprehension of one's disease and treatments.[10] Comprehension of dietary recommendations will affect compliance with dietary changes.[11] People who are lacking information regarding the relationship between dietary intake and disease progression typically select less wholesome foods.[12] Bukusuba et al.[13] indicated that while 89.5% of the participants in their study reported receiving nutrition education, only 51.9% could identify a nutritious meal. Often misconceptions regarding dietary intake and practices can negatively impact nutritional adequacy.[12]

HIV-positive persons often face barriers that affect nutritional status, including lack of a caregiver, transportation, assistance with shopping for food, preparation of food, and physical disability.[14] Furthermore, disadvantaged women with HIV experience

additional barriers to dietary changes. Compared to men, HIV-positive women have higher rates of depression, leading to greater psychosocial stress and emotional eating.[15] With better education regarding HIV-related care and regimens, these barriers can potentially be overcome.[9,10]

The barriers to attending and adhering to nutritional counseling sessions with an RD are not well documented in the HIV population. Understanding the barriers preventing persons from utilizing these services is important for the HIV community to help improve health outcomes by improving dietary intake. Furthermore, community health workers who are in contact with PLWH in Miami-Dade County are vital to the success of a nutrition program. Determining the barriers these professionals face for referring PLWH to nutritional counseling is important to increase utilization of auxiliary services in this population. This study was undertaken to identify the barriers that affect dietary counseling with an RD in PLWH.

Methods

Study Design and Setting

This was a cross-sectional study approved by the Institutional Review Board of the Florida International University. Two groups of participants were recruited; the first group was HIV-positive individuals and the second were individuals who work in healthcare and ancillary settings that deal mainly with the HIV-positive population, such as Case Managers, Medical Doctors, and Nurses. The first part of the research was conducted among HIV-positive persons currently participating in the Miami Adult Studies in HIV (MASH) cohort at the FIU Research Clinic in Borinquen Healthcare Center. Borinquen provides a variety of HIV-related services to PLWH with low

socioeconomic status in Miami-Dade County. HIV-positive people who were participating in the MASH cohort (documented HIV-positive status, ≥ 18 years) and were absent from conditions that made interviewing difficult were eligible to participate. All participants gave written informed consent and were interviewed between February and April 2014. At the study visit, a trained Dietitian completed a survey that gathered information on nutritional services. All participants were reimbursed for their time and effort in the study, which took place in a single session.

The second part of the study recruited health professionals. Locations to recruit healthcare and ancillary employees were identified using information provided by the participants recruited in the first part. Participants from healthcare and ancillary settings around Miami-Dade County were eligible to be recruited if they worked with PLWH on a routine basis. After consenting, participants completed a brief survey identifying barriers towards recommending nutritional services. Participants were offered a $5.00 gift card as appreciation for their participation in the study.

Surveys

The surveys used for this study were a modification of those used by Brunner et al.[4] and Hatsu et al.[16] Questions pertaining to the relevance were combined to form the *Barriers to Nutritional Counseling* surveys used for the participants. The *Barriers to Nutritional Counseling* survey was used for HIV-positive participants to probe information regarding the use of nutritional services. The first part of the survey sought to capture information about trusted sources of nutrition information and gathered information about nutritional services, including topics of nutrition education that participants were interested in learning about. The second part of the survey was designed

to identify the barriers preventing participants from seeing an RD, along with those that interfere with dietary advice and intake. The *Barriers to Nutritional Counseling* survey that was used for medical and ancillary personnel was used to identify barriers that professionals face when referring patients to an RD. The first part of the survey asked general questions regarding their role in nutritional services and counseling. While the second part was designed to identify specific barriers preventing the referrals of patients to an RD and left room for additional comments about barriers their patients face.

In addition to the *Barriers to Nutritional Counseling* survey that was used on HIV-positive participants, data regarding geographic characteristics and information on food security were extracted from information available from the MASH cohort.

Statistical Analysis

Data from both *Barriers to Nutritional Counseling* survey was entered into REDCap (a web-based application used to manage surveys) and then transferred to SPSS 22.0 for Windows for data analysis. Descriptive statistics were used for demographic characteristics, behavioral variables, and food security. Continuous measures are represented by means and standard deviations, using independent t-tests to measure significant differences between the two groups. Categorical data are represented by percentages, using chi-square to determine significant differences. Spearman rank correlations were used to establish the associations between the variables of interest, controlling for other variables that affected the attendance of nutritional counseling with an RD.

Results

A total of 130 HIV-positive persons completed the survey on nutritional services. The majority of participants were male (n = 79; 60.8%) and Black (n = 98; 75.4%). Approximately 45% (n = 59) of participants had a high school education, with an average monthly income of $492. While approximately 88% are currently receiving SNAP (Supplemental Nutrition Assistant Program), low household food security was reported by 16% of participants. A comparison of socio-economic characteristics between the two groups showed no significant differences between those who saw an RD compared to those who did not (Table 1).

Although 75.4% (n = 98) have seeing an RD in the past, only 46.2% (n = 60) have seen one in the past 12 months, with more than half of them (n = 70; 53.8%) not receiving any nutritional services. Of the total, 31 visited the RD 4 or more times in a year, 29 only 1 to 3 times, and 70 had not visited the RD within the year. Of those who were currently seeing an RD, 98.3% stated they would recommend the service to other HIV-infected persons, and received their care in the same place where they were followed for their HIV treatment. Ninety-eight percent of those currently seeing an RD felt that what they have learned helped with their general care, 90.0% felt that the RD provided dietary plans that they could follow and 84.0% were satisfied with their level of involvement during their appointments.

HIV-positive persons identified Medical Doctors and RD's (68.5%) as the 2 most trusted sources of nutrition information. A comparison between those seeing an RD to those who were not, showed significant differences in trusted sources. While 85.0% of persons who saw an RD stated that they trusted the RD only 54.0% that were not seeing

an RD would trust the information provided ($P = 0.001$). Furthermore, those who saw an RD were more likely to trust the radio ($P = 0.005$), and information that is based off of science and research ($P = 0.030$) (Table 2). This survey also probed participants for information on desired topics of learning interest. The topics of most interest were on concerns about their weight (74.6%), shopping healthy (72.3%), and shopping on a budget (70.0%). Both weight loss and weight gain were areas of interest in regards to weight concerns. Individuals who wanted information on shopping healthy and on a budget were concerned with comorbidities such as hypertension, high cholesterol, and diabetes. There were no significant differences between the two groups in desired educational topics (Table 3).

The most common barriers that HIV-positive persons identified with nutrition services were difficulty in keeping appointments (33.8%) such as forgetting, interference with job or other appointments, too many appointments, and lack of RD availability. Location was mentioned by 24.5% as a barrier, which included too far from other services, distance from residence, and relocation to a different area. Lack of referral to services such as changes in providers or location of HIV-related services was recognized by 23.8% as a barrier (Table 4).

Using Spearman rank correlation to determine associations, a strong positive correlation was found among certain barriers to counseling: "not referred" was correlated with being "unaware of the program" ($r = 0.433$, $P < 0.001$), "unaware of the benefits" ($r = 0.362$, $P < 0.001$), problems with "location of services" ($r = 0\ .351$, $P < 0.001$), and "cost of attendance "($r = 0.312$, $P < 0.001$), while "not being interested" was strongly

correlated with feeling that counseling was "unimportant" ($r = 0.471$, $P < 0.001$) (Table 5).

A comparison between those who received nutritional services versus those who did not receive services showed significant differences in perceived barriers toward nutritional counseling with an RD. Those who were not currently receiving nutritional services by an RD perceived their major barriers as "lack of referral (8.3 vs. 37.1%, $P = 0.001$), unaware of program (6.7 vs. 21.4%, $P = 0.017$), unaware of benefits (5.0 vs 24.3%, $P = 0.002$) and some were not interested (6.7 vs. 22.9%, $P = 0.011$)." Three participants stated that they felt like seeing an RD was not necessary due to their own nutritional knowledge.

The most commonly identified barriers toward following nutritional recommendations for the group as a whole included cost of healthy food (46.2%), not wanting to give up favorite foods (45.4%) and not wanting to give up current foods (41.5%). A comparison of the two groups showed significant differences in the barriers towards adherence to nutrition recommendations regardless of the source. Those participants who are not currently seeing an RD perceived barriers such as eating out or away from home (25.0 vs. 42.9%, $P = 0.033$), lack of willpower (21.7 vs. 40.0%, $P = 0.025$) and lack of information (10.0 vs. 34.3%, $P = 0.001$) as interfering with nutritional recommendations, compared to those seeing an RD. Individuals who did not want to give up their favorite or current foods, identified those desirable foods as greasy/ fried foods, soda, fatty foods or junk food such as cakes, cookies, and candy (Table 6).

The most common barriers that medical and ancillary professionals (n = 13) face when making referrals to an RD included patients' lack of interest (84.6%), patients'

education level (61.5%) and that the patient did not inquire about seeing an RD or nutritional services (46.2%). Among the common themes of patients' lack of interest were patients refusal or lack of follow-up. Eighty-five percent (n = 11) of the interviewed health professionals provided nutritional advice to patients. However, two of these health professionals stated that they do not believe in nutrition as therapy (Table 7).

Discussion

This is one of the first studies conducted among people living with HIV that identified the barriers that prevent individuals from seeing an RD and adhering to dietary recommendations. Similar to the results of Brunner et al.,[4] difficulty in keeping appointments was the main barrier that the group identified in this study. Participants' phone numbers frequently change or end up disconnected, therefore making it difficult to contacted and reminded of their appointment, which are often made months in advance, It is also common to schedule multiple appointments in one day; when one appointment runs longer than expected, the other one is missed. While other studies have investigated barriers for HIV treatment and adherence, studies specifically looking at nutritional services are limited. Consistent with studies looking at barriers towards ancillary services, transportation was listed at the top as a barrier for seeing an RD in this study. When individuals were provided with more than one transportation services per month, compliance with ancillary services were improved.[17]

We identified significant differences when we compared the barriers between those who saw an RD and those who did not. The results of this study showed that the high number of PLWH who are not receiving nutritional services (58.3%) may be attributed to lack of referrals or lack of education about nutritional services. Medical and

ancillary employees recruited in this study reported that referrals were mandatory at their clinics. Therefore, the referral rate in these clinics may be overstated, as this might not be the case in other clinics. However, the healthcare professionals reported multiple barriers that prevented them from making referrals to nutritional services. Similar to what Kalichman et al.[5] reported as a barrier to medical care, medical and ancillary personnel listed the patient's education level as a main barrier to referrals to RD's.

The most commonly used ancillary services by the PLWH is case management.[18] While the use of nutritional services was reported in only 9.6% of participants by Lo et al.,[18] the use of ancillary services has been significantly correlated with primary medical care.[19] Medical doctors and health care professionals providing ancillary services to HIV-positive people play a significant role in referring patients to an RD. Therefore, it is vital to educate the healthcare personnel on the importance and benefits of nutritional services. Referring patients to an RD is pivotal to ensure the patient has evidence-based education about their specific nutritional needs. Patients at different stages of the disease have markedly different dietary needs. While these healthcare professionals are referring patients on a routine basis, this study showed that the majority of them are also providing their own nutritional education without adequate credentials.

Inadequate nutritional knowledge and dietary practices in PLWH can hinder advances in medical treatment.[13] However, very little data exist concerning the nutritional knowledge of this population. Present study showed that individuals are interested in the educational materials that RD's are able to provide. However, the majority of them lack the knowledge of where to receive trusted information. It is essential that PLWH not only seek the services of an RD but follow-up on a routine basis.

While 46.2% of participants reported seeing an RD within 12-months prior to the study, 40.0% (n = 24) saw an RD one to two times during a 12-month timeframe. This study also showed, that overall, individuals trust medical doctors, nurses, and case managers for nutritional advice and, therefore, it can be inferred that they would trust their referral to an RD with experience in HIV medical nutrition management.

Limitations of this study include relying on a convenient sample from the MASH cohort, which limits generalization to other people living with HIV. The lack of research on the current topic limited available research tools. The sample size of the healthcare and ancillary personnel that we recruited was small but adequate for a pilot study. However, the results from this study may be used to improve access to nutritional services by minimizing the most prevalent barriers towards receiving nutritional services by an RD.

Investigating the particular barriers to receiving care for a given condition, location, and characteristic cultural preferences of a given population is the first step in bringing patients to care and developing or changing programs to respond to the needs of those who are supposed to benefit from the services. Understanding the barriers to receiving nutritional counseling or to referring PLWH to nutritional counseling is a critical information for designing programs to enhance the quality of HIV management, and provide meaningful and efficient solutions to these barriers. Providing transportation to patients has become an important strategy to bring patients to care, and it is an essential service for those with multiple morbidities and disabilities. Decentralizing services and bringing them closer to the clients is also a useful approach. For PLWH, the medical and nutrition care should be offered in the same location to facilitate logistics for

the participants. Appointment reminders should be provided in a form that is suitable for the communication skills and technology available to the patients, and need to be negotiated individually to be useful and successful. Nutrition education needs to be available not only to the patients, but also to the healthcare providers, as nutrition care is not perceived as important for some of them, therefore, patients are not referred to professional nutritional services.

Table 1: Table of characteristics of the population.				
	Total (n = 130)	**RD Yes (n = 60)**	**RD No (n = 70)**	***P*-value**
Age, mean (SD)	47.8 (6.5)	49.0 (5.7)	46.8 (7.0)	0.054
Gender (%)				
Male	60.8	61.7	60.0	0.848
Female	39.2	38.3	40.0	
Race/Ethnicity (%)				
White	5.4	1.7	8.6	0.821
Black	75.4	80.0	71.4	
Hispanic	16.9	18.3	15.7	
Other	2.3	0.0	4.3	
Marital Status (%)				
Single/Not Married	87.7	86.7	88.6	0.744
Married	12.3	13.3	11.4	
Education Level, mean (SD)	11.5 (3.2)	11.7 (1.9)	11.2 (4.0)	0.384
Income, mean (SD)	492.1 (466.1)	489.2 (429.2)	494.6 (498.6)	0.949
Food Security (%)				
High Food	80.1	78.3	81.4	0.914
Marginal	3.8	6.7	1.4	
Low	11.5	10.0	12.9	
Very Low	4.6	5.0	4.3	
SNAP (%)	83.0	80.0	94.0	0.013*
CD4 Cell Count, mean (SD)	484.6 (277.0)	487.3 (266.1)	482.1 (289.3)	0.879
Viral Load, mean (SD)	2.5 (1.3)	2.3 (1.3)	2.7 (1.3)	0.116
*Statistically significant $P < 0.05$				

Table 2: Trusted source for nutritional information by group.				
	Total (n = 130)	**RD Yes (n = 60)**	**RD No (n = 70)**	***P*-value**
Doctor	68.5 %	68.3 %	68.6 %	0.977
RD	68.5 %	85.0 %	54.3 %	< 0.001*
Nurse	27.7 %	31.7 %	24.3 %	0.352
Case Manager	25.4 %	26.7 %	24.3 %	0.758
Science/Research	21.5 %	30.0 %	14.3 %	0.030*
Family/Friends	18.5 %	23.3 %	14.3 %	0.188
Television	18.5 %	25.0 %	12.9 %	0.076
Internet	16.2 %	20.0 %	12.9 %	0.273
Radio	11.5 %	20.0 %	4.3 %	0.005*
*Statistically significant $P < 0.05$				

Table 3: Education information participants are interested in.				
	Total (n = 130)	**Yes (n = 60)**	**No (n = 70)**	***P*-value**
Shopping healthy	72.3 %	70.0 %	74.3 %	0.590
Shopping on a budget	70.0 %	70.0 %	70.0 %	1.00
Cooking healthy	68.5 %	68.3 %	68.6 %	0.977
Medication	58.5 %	56.7 %	60.0 %	0.703
Food safety	69.2 %	66.7 %	71.4 %	0.561
Current weight	74.6 %	76.7 %	72.9 %	0.622
Reading food labels	53.1 %	55.0 %	51.4 %	0.687
Dining out	56.9 %	51.7 %	61.4 %	0.266

Table 4: Barriers to attendance to nutrition services.				
	Total (n = 130)	**RD Yes (n = 60)**	**RD No (n = 70)**	**P-value**
Difficult to keep appointments	33.8 %	35.0 %	32.9 %	0.799
Location	24.6 %	18.3 %	30.0 %	0.126
Not Referred	23.8 %	8.3 %	37.1 %	< 0.001*
Lack of Transportation	23.1 %	21.7 %	24.3 %	0.726
Unaware of benefits	15.4 %	5.0 %	24.3 %	0.002*
Cost of Attendance	15.4 %	11.7 %	18.6 %	0.280
Not Interested	15.4 %	6.7 %	22.9 %	0.011*
Unaware of program	14.6 %	6.7 %	21.4 %	0.017*
Concern about confidentiality	10.8 %	8.3 %	12.9 %	0.411
Unimportant	10.8 %	6.7 %	14.3 %	0.165
Family/friends not supportive	4.6 %	8.3 %	1.4 %	0.062
*Statistically significant $P < 0.05$				

Table 5: Spearman correlations showing the relationships between barriers.

Barriers		Lack of Transportation	Cost of Attendance	Not referred	Location Undesirable	Unaware of Benefits	Concern about Confidentiality	Unimportant
Lack of Transportation	r =	1.000	0.272	0.293	0.365	0.222	0.281	- 0.190
	P-value	.	0.002*	0.001*	< 0.001*	0.011*	0.001*	0.030*
Difficulty in Keeping Appointments	r =	0.341	0.281	0.134	0.233	0.146	0.223	- 0.091
	P-value	< 0.001*	0.001*	0.129	0.008*	0.098	0.011*	0.302
Not Referred	r =	0.293	0.312	1.000	0.351	0.362	0.155	- 0.194
	P-value	0.001*	< 0.001*	.	< 0.001*	< 0.001*	0.078	0.027*
Cost of Attendance	r =	0.272	1.000	0.312	0.400	0.350	0.196	- 0.011
	P-value	0.002*	.	< 0.001*	< 0.001*	< 0.001*	0.026*	0.905
Concern about Confidentiality	r =	0.281	0.196	0.155	0.320	0.196	1.000	- 0.121
	P-value	0.001*	0.026*	0.078	< 0.001*	0.026*	.	0.171
Location Undesirable	r =	0.365	0.400	0.351	1.000	0.152	0.320	- 0.141
	P-value	< 0.001*	< 0.001*	< 0.001*	.	0.084	< 0.001*	0.110
Unaware of Program	r =	0.187	0.306	0.433	0.219	0.487	0.137	- 0.144
	P-value	0.033*	< 0.001*	< 0.001*	0.012*	< 0.001*	0.119	0.103
Unaware of Benefits	r =	0.222	0.350	0.362	0.152	1.000	0.196	0.196
	P-value	0.011*	< 0.001*	< 0.001*	0.084	.	0.026*	0.026*
Unimportant	r =	- 0.190	- 0.011	- 0.194	- 0.141	0.196	- 0.121	1.000
	P-value	0.030*	0.905	0.027*	0.110	0.026*	0.171	.
Not Interested	r =	- 0.183	0.055	0.012	- 0.095	0.114	- 0.079	0.471
	P-value	0.037*	0.538	0.896	0.281	0.198	0.369	< 0.001*

*Statistically significant $P < 0.05$

Table 6: Barriers adhering to nutritional recommendations.				
	Total (n = 130)	**RD Yes (n = 60)**	**RD No (n = 70)**	***P*-value**
Cost of healthy food	46.2 %	38.3 %	52.9 %	0.099
Don't want to give up favorite foods	45.4 %	41.7 %	48.6 %	0.434
Don't want to give up current foods	41.5 %	38.3 %	44.3 %	0.496
Eating out/away from home	34.6 %	25.0 %	42.9 %	0.033*
Taste of healthy food	32.3 %	31.7 %	32.9 %	0.886
Lack of willpower	31.5 %	21.7 %	40.0 %	0.025*
Cultural preference	26.2 %	18.3 %	32.9 %	0.061
Lack of information	23.1 %	10.0 %	34.3 %	0.001*
No sense of urgency	15.4 %	10.0 %	20.0 %	0.117
Family/friends not supportive	4.6 %	1.7 %	7.1 %	0.140
*Statistically significant $P < 0.05$				

Table 7: Barriers toward making referrals identified by healthcare and ancillary workers.	
	n = 13
Pt Not Interested	84.6%
Education Level of Patient	61.5%
Not Asked	46.2%
Lack of Support	38.5%
Hours of RD	38.5%
Non-Adherence	30.8%
Language Barrier	30.8%
Don't Believe in Nutrition as Therapy	15.4%
Cost of Attendance	15.4%
Location of RD	7.7%
Unaware of RD in Area	7.7%
Too Busy to Refer	7.7%

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CHAPTER V: DIET QUALITY AND NUTRITIONAL STATUS OF HIV-POSITIVE INDIVIDUALS FROM THE MASH COHORT: THE BENEFITS OF NUTRITIONAL COUNSELING BY A REGISTERED DIETITIAN

Abstract

Objective: The impact of nutritional counseling on dietary intake and nutritional parameters in an HIV-positive population has not been measured. In this study, we evaluated the relationship of nutritional counseling by a Registered Dietitian (RD) on nutritional intake, diet quality, nutritional status, disease progression, and substance abuse in an HIV-positive population.

Methods: This was a cross-sectional study of a consecutive convenience sample of 130 PLWH on stable ART, who were recruited from the Miami Adult Studies on HIV (MASH) cohort. After consenting, participants completed a survey on types and frequency of nutritional services received in the last 12 months. Participants were assigned to groups according to their responses. During the Parent Study visits, body composition, vital signs, dietary and laboratory data were collected. Blood was drawn for biochemical measurements of nutritional status, and laboratory profiles were obtained from participants medical charts. The Alternate Healthy Eating Index (AHEI) scores were calculated from 24-hour dietary recalls and used to evaluate quality of the diet. Student t-tests and chi-square will be used to compare differences in the groups related to nutrition counseling. Linear regression models were used to compute the beta (β) for comparisons between the two groups. Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.

Results: Participants had a mean age of 47.8 years, 62.0% were male, and 77.0% were Black. Participants who were counseled by an RD had significantly higher AHEI scores (34.7 vs. 29.2, $P < 0.001$), lower waist circumference (35.5 vs. 38.5 inches, $P = 0.003$), lower systolic blood pressure (114.8 vs. 127.9 mmHg, $P < 0.001$), lower diastolic blood pressure (75.5 vs. 84.1 mmHg, $P < 0.001$) compared to those who had not seen an RD in the past year. There were no significant differences in socio-demographics or fasting blood glucose between the groups.

Conclusions: Receiving nutritional counseling improved dietary intake, nutritional status, and clinical outcomes in a cohort of people living with HIV (PLWH).

Keywords: HIV, Nutrition counseling, Alternative Health Eating Index (AHEI)

Background

Malnutrition, which begins early in the course of HIV-infection, is common among people living with HIV (PLWH) and contributes to HIV disease progression.[1] Moderate to severe malnutrition, when initiating antiretroviral therapy (ART) has been associated with a 6-fold increase in mortality.[2] Individuals with a lower body mass index (BMI), middle upper arm circumference (MUAC), or hemoglobin (Hgb) levels had a higher risk of death 3 months after ART initiation.[3] Complications of malnutrition that have been reported in HIV-infected persons include impaired physical activity, worsened general health, gastrointestinal symptoms, altered dietary intake, and weight loss.[4]

Micronutrient deficiencies, which are commonly observed in HIV, have been associated with HIV-disease progression and mortality.[5] Supplementation of micronutrients has shown to reduce the rate of HIV-disease progression and AIDS-defining conditions in PLWH.[6] Furthermore, nutritional supplementation has shown to

improve malnutrition, mainly by helping participants consume at least 80% of daily requirements.[7] However, the level of compliance with therapeutic nutritional supplementation is often low due to the taste of the supplement and the monotony of the diet.[8] When compliance is observed, significant improvements have been seen with an average daily weight gain of 1.6 g/kg/day and a median weight gain of 8 kg in approximately 4-months.[9]

Nutritional support can improve nutritional status and health outcomes by improving dietary intake in PLWH.[10] Decrease in the consumption of high fat and high sugar foods were seen after a brief intervention, with reductions seen primarily in the intake of sugar-containing sodas and fried foods.[10] Furthermore, counseling has been shown effective for weight gain in lower socioeconomic class individuals who suffer a high rate of food insecurity.[11] A balanced diet is critical for PLWH because it supports the immune response and promotes health. The Academy of Nutrition and Dietetics recommends that PLWH seek the services of a Registered Dietician (RD) on a routine basis.[12] However, dietary services are one of the most underutilized ancillary services with a reported participation rate of 9.6%.[13] To date, very little information is available regarding the direct benefit that an RD has on the health outcomes in PLWH. Therefore the aim of this study was to investigate the relationship of nutrition counseling with an RD on diet quality, nutritional status, and disease outcomes in PLWH compared to those who are not currently seeing an RD.

Methods

This was a cross-sectional study of a consecutive convenience sample of 130 PLWH on stable ART, who were recruited from the Miami Adult Studies in HIV

(MASH) cohort at the FIU Research Clinic in Borinquen Healthcare Center. All participants in the MASH cohort were 18 years or older and have documented HIV status in their medical charts. Borinquen provides a variety of HIV-related services to persons with low socioeconomic status living with HIV/AIDS in Miami-Dade County. PLWH who were part of the MASH cohort, receiving ART for more than 6 months, and were absent from conditions that made interviewing difficult were eligible to participate. All participants gave written informed consent and were interviewed between February and April 2014. At the study visit, participants completed a questionnaire that gathered information on nutritional services, which was used to determine group assignments. Participants who were seeing an RD while enrolled in the MASH cohort were compared to participants who were not receiving nutritional services with an RD while enrolled in the MASH cohort. Individuals who were missing information from their charts were excluded from the study, leaving a sample size of 100. All participants were reimbursed $5.00 for the time and effort dedicated to this study. Study was conducted in a single session. This study was approved by the Institutional Review Board at Florida International University.

Interview Data

Demographic information, HIV-related events and therapy, drug usage, food security and dietary intake information were gathered during individual interviews as part of the MASH cohort by a trained Graduate Research Assistant.

Dietary Intake

The average of two 24-hour dietary recalls was used to assess diet intake and quality. The two recalls, which were selected based on dates that participants reported

seeing an RD, were conducted 12-months from each other by a trained Graduate Research Assistant. Food intake data was converted into energy and nutrients using Nutribase 9.0. Information extracted from Nutribase included: calorie intake, total fat, saturated fat, total carbohydrates, protein, and total fiber. Dietary intake outcomes were then used to calculate the AHEI score using the method from McCullough et al.[14] The AHEI score is based on the following nine components: vegetables, fruits, nuts and soy, ratio of white meat to red meat, cereal fiber, *trans* fat, the ratio of polyunsaturated fatty acids to saturated fatty acids, duration of multivitamin usage, and moderate alcohol consumption. All nine components were summed up to provide an overall AHEI score which could range from 2.5 to 87.5. Each component provided between 0-10 points, except the multivitamin component which was dichotomous and contributed either 2.5 points (for nonuse) or 7.5 (for use).[14]

Drug and Alcohol Usage

Scores provided from the AUDIT questionnaire[15] were used to determine misuse of alcohol. Scores equal or higher than 8 indicate harmful or hazardous drinking tendencies. Scores indicative of alcohol dependency are gender dependent; for women dependency is classified as having a score of 13 or more and for men the score is 15 or more. A validated drug use questionnaire[16,17] was administered verbally that detailed the type, frequency, mode of administration, and illicit drug use in the previous 6 months. At the same visit, urine samples were taken and analyzed for evidence of drug abuse using toxicology urine kits (American Bio Medica Corp. Kinderhook, NY) for the presence of barbiturates, benzodiazepines, cannabinoids, hallucinogens, morphine, and amphetamines.

Food security

Food security status was determined using the US Household Food Security Survey Module[18], which measured food availability, access, and sufficiency over a 12 months period.[19] Following standard procedures, responses were coded, and food security scores were calculated. This was used to classify patients into following categories:

- For scores of 0-1: high/marginal food security – little or no indication of limitation with food access or changes in diet quality and food intake;
- For scores of 2-4: low food security- reports of reduction in diet quality, with little or indication for reduction in food intake;
- For scores of 5-6: very low food security- Several indications of disruptions with eating patterns reported, in addition to reduction in food intake.

Physical Examination

A physical examination and medical history were performed by a trained nurse under the supervision of a physician. Weight and height were obtained with participants wearing light clothing and no shoes. Weight, which was determined utilizing a standard scale calibrated prior to each measurement, was rounded to the nearest .01 kilogram. Height, which was measured with the participant's heels touching the base of the vertical board of the stadiometer, was rounded to the nearest .01 inch. Anthropometrics were also obtained by trained personnel, and body mass index (BMI) was calculated by dividing the weight in kilograms by height in meters squared. Waist and hip circumference was measured using a tape measure. Waist circumference was measured at the narrowest part of the waist between the lowest rib and the iliac crest and the hip circumference at the widest portion of the buttocks. Bioelectrical impedance analysis (BIA) using the

Biodynamics body composition analyzer (model BIA-450; Biodynamics Corp., Seattle, WA), determined impedance and calculated body composition. Subjects were measured, lying down, without shoes and socks, and electrodes were placed on the participant's right hand and wrist and right foot and ankle. Blood pressure was measured in the left arm with the elbow flexed to heart level techniques.

Biochemical data and Laboratory Values

Fasting blood samples were drawn for the assessment of hemoglobin, hematocrit, albumin, fasting glucose, zinc, and selenium. Blood samples were analyzed by a commercial laboratory for levels of hemoglobin, hematocrit, and albumin, while levels of zinc and selenium were processed at Dr. Baum's Nutrtion Research Laboratory at FIU. Information regarding lipid profiles, CD4 cell counts, and viral loads was abstracted from values in the participants' medical records accessed with their written permission.

Statistical Analysis

SPSS-22 was used for statistical analyzes and *P*-value less than 0.05 were considered significant. Frequency and descriptive statistics were calculated for all variables. Student's t-test was used to assess differences between the two groups, and chi-square was used for categorical variables. Linear regression models were used to compute the beta (β) for comparisons between the two groups. Models were adjusted for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.

Results

The demographic, anthropometric and CVD risk factors are presented in Tables 1 and 2. The majority of participants (n = 100) were male (62.0%) and Black (77.0%).

Approximately 73.0% of participants had a high school education, with an average monthly income of $472. While approximately 89.0% are currently receiving nutrition assistance through the Supplemental Nutrition Assistance Program (SNAP), low household food security was reported by 11% of participants. A comparison of socio-economic characteristics between the two groups showed no significant differences between those who saw an RD compared to those who did not (Table 1).

Although 76.0% (n = 76) have seen an RD in the past, only 48.0% (n = 48) have seen one in the past 12 months, with almost one-quarter of them (n = 24; 24.0%) reporting never receiving nutritional services. Of those who were currently seeing an RD, 47.9% visited the Dietitian 4 or more times in a year, 11 only 1 time, and 76 have no nutritional intervention. On average, participants reported that they had been attending lasted 43.7 minutes.

Analysis of 24-hour recalls showed that HIV-positive individuals who saw an RD had significantly higher AHEI scores (34.7 vs. 29.2; $P = < 0.001$) compared to those who were not currently seeking nutritional services with an RD. Significant differences were found in the AHEI components for cereal fiber ($P = 0.021$) and multivitamin usage ($P = 0.003$) among those who attended counseling with an RD. While the difference was only approaching significance, the participants who had been seen by an RD also had higher intakes of nuts and soy products ($P = 0.071$), and the ratio of white meat to red meat ($P = 0.098$) (Table 2). PLWH, who saw an RD, as compared to those who did not, were more likely to consume more dietary fiber (16.61 vs. 12.05 grams; $P = 0.028$). However, nutrition counseling did not have a significant impact on the specific types of nutrient intake such as energy, protein, carbohydrate, total fat, and saturated fat. (Table 3)

Table 4 shows that the AHEI-scores and total energy intakes were significantly higher among those who had seen an RD compared to those who had not. The test for slope was significant for both AHEI and total energy with *P*-values of less than 0.001 and 0.027 respectively, indicating a dose-response effect for the RD group.

Significant differences were seen in the group who had been attending nutritional counseling sessions during anthropometric and body composition measurements. Individuals who had seen an RD had lower BMI (26.0 vs. 28.8; $P = 0.019$), WC measurements (35.5 vs 38.5 inches; $P = 0.003$), and fat mass (46.7 vs. 57.8; $P = 0.032$). (Table 5) Furthermore, 71.2% of participants who had not seen an RD were categorized as overweight, obese, or morbidly obese. The test for slope was significant for BMI ($P = 0.025$), waist circumference ($P = 0.005$), and fat mass ($P = 0.038$), indicating a dose-response effect for the RD group (Table 6).

Lower levels of total cholesterol, LDL, triglycerides, BMI, and fat mass were observed among those who saw an RD, as compared to those who did not consult an RD. Consulting an RD was significantly associated with higher HDL-cholesterol levels. However, we did not find any significant differences between the two groups in other nutritional laboratory parameters (Table 5 and Table 7). The group that consulted an RD had significantly lower rate of individuals with undetectable viral loads compared to those who did not consult an RD. (54.0% vs. 75.0%; $P = 0.029$). However, no difference was observed between the two groups in CD4 cell counts.

As shown in Table 8, there were no significant differences in substance abuse between the two groups. However, those consulting an RD reported a greater amount of substance use for all outcomes measured. Sixty-three percent of the cohort tested

positive for at least 1 of the 7 drugs tested for, while 26.0% tested positive for marijuana and crack/cocaine. Sixty-six percent reported smoking cigarettes with an average of 3 per day, and 59.0% reported alcohol intake with an average of 2 drinks per day. Comparison of the AUDIT score (Figure 1), a greater number of participants who saw an RD reported harmful/hazardous drinking levels and alcohol dependence, while 21.0% from both groups reported binge drinking.

Participants who consulted an RD tended to demonstrate better nutritional parameters. Significant anthropometric differences were also observed between the groups. The group of participants who attended nutritional counseling sessions with an RD had a higher proportion of people within normal limits of their BMI, a lower waist to hip ratio, and lower percent body fat. No significant differences were found in the laboratory parameters between the two groups.

Discussion

To our knowledge, this is the first observational study to look at the direct impact of nutritional counseling by an RD has on PLWH. Nutritional inadequacy is common in individuals with HIV and compromises health outcomes.[1-3,5] Intervention studies that offer nutrition counseling have shown to be effective in improving dietary intake.[10,11] Studies that provided dietary intervention demonstrated an increase in the intake of fruits, vegetables and food high in dietary fiber.[10] However, in our cohort, the intake of fruits and vegetables was low for the group receiving dietary counseling. Similar to Segal-Isaacson et al.[10] individuals who consulted an RD had significantly more fiber intake compared to those not seeing an RD.

Significant differences were noticed in anthropometric and body composition outcomes. Individuals who were attending nutritional counseling by an RD had significantly better BMI, waist circumference, and fat mass measurements. Similar to our findings, several studies reported significant improvements in weight and BMI changes after nutritional intervention for weight management. [11,20-22] An intervention study by Roubenoff et al.[22] reported additional improvements in waist circumference and body fat similar to the ones found in our cohort.

No significant differences were found in laboratory parameters for hemoglobin, hematocrit, albumin, or fasting blood glucose. However, individuals who attended nutritional counseling by an RD had significantly better lipid profile compared to those who did not see an RD. Similarly, lipid profiles that included total cholesterol, HDL, LDL, and triglycerides were improved after dietary counseling that addressed lipodystrophy.[21,22]

While no significant differences were found with substance use, it is important to note that some of the individuals who were seeing an RD were doing so as part of a substance abuse program. Studies have shown that offering nutrition education during substance abuse programs has decreased substance use and improved the quality of dietary intake.[23,24]

The limitations of this study include the use of 24-hour recalls to determine AHEI components, which was designed to be used with food frequency questionnaires. Furthermore, while 24-hour recalls are a reliable tool, their reliability depends on the participants' ability to recount their dietary consumption with fidelity. Furthermore, the data from the parent study were not collected with the specific outcomes of this study;

therefore, the sample size was reduced due to missing data. Lastly, the external validity of the study is also decreased because we used a convenience sample of limited geographic and ethnic distribution.

This is the first known observational study to analyze the nutritional benefits of consulting an RD for PLWH. While persons seeing an RD had significantly higher AHEI scores, mean scores of dietary intake still need improvement in both groups, especially in the areas of fruit and vegetable intake. In conclusion, PLWH who attended nutritional counseling had significantly better nutritional outcomes compared with persons not seeing an RD.

Table 1: Table of characteristics of the population.				
	Total (n = 100)	**RD Yes (n = 48)**	**RD No (n = 52)**	***P*-value**
Age, mean (SD)	47.8 (6.8)	47.5 (7.3)	48.1 (6.4)	0.692
Gender (%)				
Male	62.0	58.3	34.6	
Female	38.0	41.7	65.4	0.473
Marital Status (%)				
Single	87.0	89.6	84.6	
Married	13.0	10.4	15.4	0.466
Race/Ethnicity (%)				
White	7.0	10.4	3.8	
Black	77.0	75.0	11.5	
Hispanic	11.0	10.4	78.8	
Other	5.0	4.2	5.8	0.287
Income, mean (SD)	472.3 (474.9)	410.9 (431.5)	528.9 (509.4)	0.216
Education, mean (SD)	11.5 (2.7)	11.2 (3.4)	11.80 (1.9)	0.297
Food Security (%)	89.0	90.4	87.50	0.914
SNAP (%)	89.0	83.0	94.0	0.013*
*Statistically significant $P < 0.05$				

Table 2: AHEI scores comparison between groups.

Components	Criteria for min. scores	Criteria for max. scores	Possible score range	Total (n = 100)	RD Yes (n = 48)	RD No (n = 52)	*P*-value
Vegetable (serving/day)	0	5	0-10	1.4 (1.5)	1.4 (1.5)	1.4 (1.5)	0.903
Fruit (serving/day)	0	4	0-10	2.0 (2.2)	2.2 (2.2)	1.8 (2.1)	0.426
Nuts and Soy (serving/day)	0	1	0-10	0.4 (1.5)	0.6 (1.7)	0.1 (0.7)	0.071*
Ratio of white to red meat	0	4	0-10	4.1 (3.2)	4.6 (3.2)	3.6 (3.2)	0.098
Total Fiber (% of energy)	0	24	0-10	7.1 (2.4)	7.6 (2.1)	6.5 (2.5)	0.021*
Trans Fat (% of energy)	≥ 4	≤ 0.5	0-10	10.0 (0.1)	10.0 (0.0)	9.9 (0.1)	0.339
Ratio of PUFA to SFA	≤ 0.4	≥ 1	0-10	3.1 (2.2)	3.3 (2.2)	2.9 (2.1)	0.310
Duration of multivitamin use	< 5 years	≥ 5 years	2.5-7.5	2.9 (3.1)	3.9 (3.1)	2.0 (2.9)	0.003*
Alcohol (servings/day) **Men** **Women**	 0 or > 3.5 0 or > 2.5	 1.5-2.5 0.5-1.5	 0-10 0-10	1.0 (2.0)	1.2 (2.1)	0.9 (1.9)	0.482
Total Score			2.5-87.5	31.8 (7.6)	34.7 (7.7)	29.2 (6.5)	< 0.001*

Abbreviation: PUFA = Polyunsaturated fatty acids; SAF = Saturated fatty acids.
Each AHEI component contributed from 0-10 points to the total AHEI score, except the multivitamin component which was dichotomous and contributed either 2.5 points (for nonuse) or 7.5 (for use). A score of 10 indicates that the recommendations were fully met, whereas a score of 0 represents the least healthy dietary behavior. Intermediate intakes were scored proportionately between 0 and 10.

*Statistically significant $P < 0.05$
** Components are reported as the mean and standard deviation (SD)

Table 3: Dietary intake comparison between groups.				
	Total (n = 100)	**RD Yes (n = 48)**	**RD No (n = 52)**	***P*-value**
Energy Kcal, mean (SD)	2132.00 (919.56)	2309.75 (900.88)	1967.92 (914.51)	0.063
Protein g, mean (SD)	87.95 (35.14)	92.03 (35.69)	84.12 (34.53)	0.259
Carbohydrate g, mean (SD)	258.80 (113.21)	278.72 (106.36)	240.41 (117.19)	0.091
Fiber g, mean (SD)	14.24 (10.44)	16.61 (12.85)	12.05 (7.01)	0.028*
Fat g, mean (SD)	78.16 (45.71)	82.44 (48.54)	74.21 (43.03)	0.371
Saturated Fat g, mean (SD)	26.21 (18.94)	28.23 (22.78)	24.34 (14.50)	0.307
Zinc mg, mean (SD)	9.60 (6.39)	10.45 (7.45)	8.81 (5.18)	0.203
*Significance *P*-value < 0.05				

Table 4: Linear regression for dietary intake comparisons between the two groups.			
	β	**95% Confidence**	***P*-value**
AHEI-score	5.774	2.884, 8.664	< 0.001*
Energy Kcal	397.421	45.204, 749.638	0.027*
Protein g	9.551	-4.379, 23.481	0.177
Carbohydrate g	41.155	-3.838, 86.147	0.073
Fiber g	3.842	-0.388, 8.072	0.075
Fat g	11.120	-7.315, 29.556	0.234
Saturated Fat g	5.460	-2.017, 12.937	0.150
Zinc mg	1.900	-0.644, 4.445	0.141
*Significance *P*-value < 0.05 **Controlled for age, gender, education, income, marriage, AUDIT score, urine toxicity ***Each model ran independent			

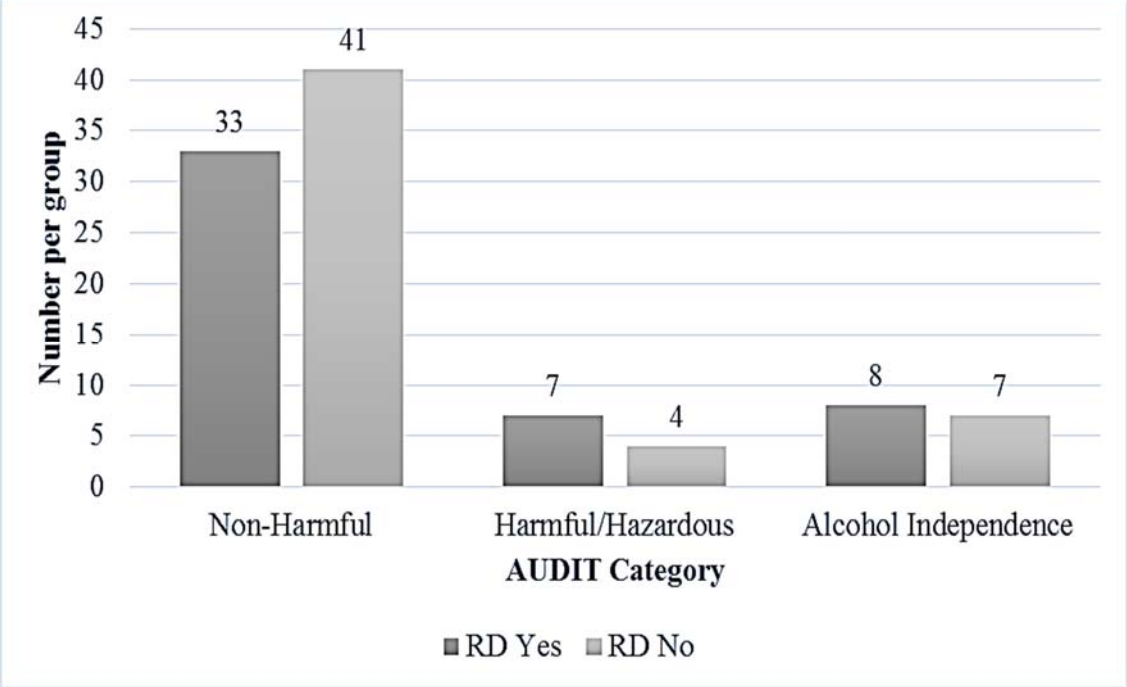
Table 5: Comparisons between groups.				
	Total (n=100)	**RD Yes (n=48)**	**RD No (n=52)**	***P*-value**
Diet Quality				
AHEI-Score, mean (SD)	31.8 (7.6)	34.7 (7.7)	29.2 (6.5)	< 0.001**
Anthropometrics				
BMI (kg/m^2), mean (SD)	27.4 (5.9)	26.0 (5.2)	28.8 (6.2)	0.019**
Waist (inch), mean (SD)*	37.1 (5.1)	35.5 (4.7)	38.5 (5.1)	0.003**
Waist:Hip (inch), mean (SD)	0.9 (0.1)	0.9 (0.1)	0.9 (0.1)	0.177
Body Composition				
Fat Mass (%), mean (SD)	52.5 (25.8)	46.7 (23.0)	57.8 (27.2)	0.032**
Fat %, mean (SD)	28.4 (10.5)	27.0 (10.2)	29.7 (10.6)	0.187
BCM, mean (SD)	63.6 (15.1)	60.9 (12.9)	66.1 (16.6)	0.082
BCM %, mean (SD)	36.7 (8.9)	27.0 (10.2)	29.7 (10.6)	0.934
Laboratory Parameters				
Total Cholesterol, mg/dL, mean (SD)	178.5 (39.0)	166.9 (37.0)	189.2 (38.0)	0.004
HDL, mgl/dL, mean (SD)*	49.9 (12.9)	53.4 (13.5)	46.7 (11.6)	0.009
LDL, mg/dL, mean (SD)	103.4 (33.4)	93.4 (31.1)	112.8 (33.0)	0.003
Triglycerides, mg/dL, mean (SD)*	140.6 (75.3)	110.8 (57.6)	168.1 (79.6)	< 0.001
Hemoglobin mg/dL , mean (SD)	13.8 (1.4)	13.3 (1.3)	13.6 (1.4)	0.211
Hematocrit %, mean (SD)	41.6 (4.8)	41.3 (5.1)	41.9 (4.5)	0.585
Albumin mg/dL, mean (SD)	4.2 (0.3)	4.2 (0.3)	4.1 (0.3)	0.665
Blood Glucose mg/dL, mean (SD)*	101.3 (32.5)	101.2 (30.6)	101.3 (34.5)	0.990
Homocysteine mg/dL, mean (SD)	10.1 (3.6)	9.5 (2.4)	10.7 (4.3)	0.083
Zinc mg/dL, mean (SD)	0.7 (0.2)	0.7 (0.2)	0.7 (0.2)	0.806
Selenium mg/dL, mean (SD)	0.1 (0.0)	0.1 (0.0)	0.1 (0.0)	0.305
Disease Progression				
Viral Load, $\log_{10}$ mean (SD)	2.5 (1.3)	2.3 (1.3)	2.7 (1.3)	0.116
CD4 Cell Count, mean (SD)	484.6 (277.0)	487.3 (266.1)	482.1 (289.3)	0.925
Other Outcomes				
Systolic BP mmHg, mean (SD)*	121.6 (18.2)	114.8 (15.4)	127.9 (18.5)	< 0.001**
Diastolic BP mmHg, mean (SD)*	80.0 (11.8)	75.5 (9.4)	84.1 (12.4)	< 0.001**
**Statistically significant $P < 0.05$				

Table 6: Linear regression for anthropometric comparisons between the two groups.			
	β	**95% Confidence**	***P*-value**
BMI kg/m^2	-2.624	-4,918, -0.329	0.025*
Waist Circumference (inch)	-2.911	-4.910, -0.911	0.005*
Waist:Hip	-0.015	-0.038, 0.008	0.205
BCM	-5.587	-11.707, 0.532	0.073
BCM %	-0.439	-4.610, 3.282	0.815
Fat Mass (%)	-10.638	-20.669, -0.607	0.038*
Fat %	-2.553	-6.661, 1.555	0.220
*Significance *P*-value < 0.05 **Controlled for age, gender, education, income, marriage, AUDIT score, urine toxicity ***Each model ran independent			

Table 7: Linear regression for biochemical comparisons between the two groups.			
	β	**95% Confidence**	***P*-value**
Hemoglobin mg/dL	-0.434	-0.949, 0.082	0.098
Hematocrit %	-0.621	-2.557, 1.315	0.526
Glucose mg/dL	0.621	-12.638, 13.880	0.926
Albumin mg/dL	0.038	-0.086, 0.163	0.542
Zinc mg/dL	-0.019	-0.411, 0.073	0.682
Selenium mg/dL	0.011	-0.009, 0.030	0.281
CD4 Cell Count cell/µg	-15.727	-120.065, 88.611	0.765
Viral Load, $\log_{10}$	-0.404	-0.900, 0.093	0.110
*Significance *P*-value < 0.05 **Controlled for age, gender, education, income, marriage, AUDIT score, urine toxicity ***Each model ran independent			

Table 8: Comparison of drug usage between groups.				
	Total (n = 100)	**RD Yes (n = 48)**	**RD No (n = 52)**	***P*-value**
Smoking (%)	66.0	70.8	61.5	0.332
Frequency, mean (SD)	3.1 (2.4)	3.3 (2.3)	2.9 (2.4)	0.388
Drinking (%)	59.0	60.4	57.7	0.785
Frequency, mean (SD)	2.0 (2.1)	1.8 (2.1)	2.1 (2.2)	0.537
AUDIT, mean (SD)	5.4 (7.3)	5.7 (7.8)	5.1 (6.9)	0.698
Marijuana (%)	26.0	31.3	21.2	0.225
Frequency, mean (SD)	0.8 (1.6)	1.0 (1.7)	0.6 (1.4)	0.223
Urine Toxicology (%)	55.0	60.4	50.0	0.300
Cocaine/Crack (%)	26.0	33.3	19.2	0.110
Frequency, mean, (SD)	0.5 (1.0)	0.6	0.4	0.338
Urine Toxicology (%)	42.0	50.0	34.6	0.122
Overall Toxicology (%)	63.0	68.8	57.7	0.257
*Urine Toxicology are reported as % positive				

Figure 1: Group Comparison of AUDIT Score



Legend: There were not significant differences in the AUDIT score between individuals who consulted an RD and those who did not consult an RD.

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CHAPTER VI: CARDIOVASCULAR BENEFITS ASSOCIATED WITH NUTRITIONAL COUNSELING IN PEOPLE LIVING WITH HIV (PLWH) IN THE MIAMI ADULT STUDIES ON HIV (MASH) COHORT

Abstract

Objective: Cardiovascular disease (CVD) has become one of the main non-AIDS-related causes of death in HIV-positive adults on antiretroviral therapy (ART). We compared HIV-positive adults who were followed by a Registered Dietitian (RD) to those who were not currently followed by an RD on the incidence and risk factors of metabolic syndrome (MetS), and their CVD risk.

Methods: This was a cross-sectional study of a consecutive convenience sample of 130 PLWH on stable ART, who were recruited from the Miami Adult Studies on HIV (MASH) cohort. After consenting, participants completed a survey on types and frequency of nutritional services received in the last 12 months. Participants were assigned to groups according to their responses. Vital signs and blood pressure were taken, blood was drawn for fasting glucose and homocysteine, and lipid profiles obtained from medical charts. MetS was defined by the 5 NCEP ATP III risk factors. People with ≥ 3 risk factors were identified as having MetS. The Framingham Risk Score (FRS) was used to determine the 10-year probability of CVD. Student t-tests and chi-square will be used to determine if nutritional counseling is associated with differences in CVD risk factors between the two groups. Linear regression models were used to compute the beta (β) for comparisons between the two groups. Adjustment was made for age, gender, education, marital status, alcohol intake based on the AUDIT score, and urine toxicology for overall drug intakes.

Results: Participants had a mean age of 47.8 years, 62.0% were male, and 77% were Black, and 27% had MetS. Participants who were counseled by an RD had significantly higher HDL levels (53.4 vs. 46.7mg/dL, $P = 0.009$), lower waist circumference (WC) (35.5 vs. 38.5 inches, $P = 0.003$), lower systolic blood pressure (114.8 vs. 127.9 mmHg, $P < 0.001$), lower diastolic blood pressure (75.5 vs. 84.1 mmHg, $P < 0.001$), and lower triglycerides (110.8 vs. 168.1, $P < 0.001$) compared to those who had not seen an RD in the past year. There were no significant differences in demographics, fasting blood glucose or homocysteine levels between the groups.

Conclusions: These results suggest that receiving nutritional counseling decreases the risks for MetS and other related CVD risk factors.

Keywords: Cardiovascular risk factors, nutrition counseling, metabolic syndrome

Background

Current treatment for HIV infection has dramatically reduced mortality;[1] however, comorbidities such as CVD are now becoming a concern within the HIV population.[2] CVD is the main non-AIDS related cause of death in HIV-positive individuals on ART.[2,3] MetS, which is a cluster of risk factors that increase the chance of developing CVD, is currently estimated at 33% for people living with HIV (PLWH).[4,5] According to the National Cholesterol Education Program/Adult Treatment Panell III (NCEP ATPIII) criteria, MetS is defined by three or more of the following features: abdominal obesity, hypertension, dyslipidemia, and insulin resistance.[6-8]

The increased prevalence of CVD is multifactorial, involving intervention factors such as use of ART, which increases CVD risk by 16%, and other lifestyle

factors,[2] such as an atherogenic diet, lack of physical activity, smoking, alcohol and illicit drug use.[2] Metabolic factors also contribute to the increase in CVD rates in PLWH.[9] Traditional risk factors including hypertension, dyslipidemia and diabetes are also increased in PLWH, accounting for a 25% increase in CVD risk.[10] An increase in triglyceride levels is often the most pronounced lipid abnormality in HIV-positive individuals.[11] An 11% increased risk for having myocardial infarction (MI) was associated with each 2-fold increase in triglycerides.[12] Short-term ART has been associated with a decrease in HDL levels and an increase in total cholesterol levels,[9] while continuous use for more than 3 years was associated with dyslipidemias, which included increased triglyceride, total and LDL cholesterol levels.[13] When waist circumference is increased along with triglycerides, the risk of insulin resistance, MetS, and CVD risk determined with the Framingham Risk Scoring (FRS) increases.[14] The presence of lipodystrophy and elevated CD4 cell counts further increase the chance of CVD.[15] Smoking was the biggest contributing factor for individuals with MetS, increasing FRS by more than 10%.[15]

The aim of this study was to compare HIV-positive adults who received dietary intervention from a Registered Dietitian (RD) with those who did not, in risk factors of MetS and their 10-year risk for CVD.

Methods

This was a cross-sectional study of a consecutive convenience sample of 130 PLWH on stable ART, who were recruited from the Miami Adult Studies in HIV (MASH) cohort at the FIU Research Clinic in Borinquen Healthcare Center. All participants in the MASH cohort were 18 years or older and have documented HIV

status in their medical charts. Borinquen provides a variety of HIV-related services to persons with low socioeconomic status living with HIV/AIDS in Miami-Dade County. PLWH who were part of the MASH cohort, receiving ART for more than 6 months, and were absent from conditions that made interviewing difficult were eligible to participate. All participants gave written informed consent and were interviewed between February and April 2014. At the study visit, participants completed a survey that gathered information on nutritional services, which was used to identify the group assignment for each participant. Individuals who were missing information from their charts were excluded from the study, leaving a sample size of 100. All participants were paid $5.00 as reimbursement for time and effort in the study, which was completed in a single session. This study was approved by the Institutional Review Board at Florida International University.

Interview Data

As part of the MASH cohort studies, a trained Graduate Research Assistant gathered information for demographics, HIV-related events, and therapy, drug use, and food security.

Drug and Alcohol Usage

Scores provided from the AUDIT questionnaire[16] were used to determine misuse of alcohol. Scores equal or higher than 8 indicate harmful or hazardous drinking tendencies. Scores indicative of alcohol dependency are gender dependent; for women dependency is classified as having a score of 13 or more and for men the score is 15 or more. A validated drug use questionnaire[17,18] was administered verbally that detailed the type, frequency, mode of administration, and illicit drug use

in the previous 6 months. At the same visit, urine samples were taken and analyzed for evidence of drug abuse using urine toxicology kits (American Bio Medica Corp. Kinderhook, NY) for the presence of barbiturates, benzodiazepines, cannabinoids, hallucinogens, morphine, and amphetamines.

Food security

Food security status was determined using the US Household Food Security Survey Module, which measured food availability, access, and sufficiency over a 12 months period.[19] Following standard procedures, responses were coded, and food security scores were calculated. This was used to classify patients into following categories:

- For scores of 0-1: high/marginal food security – little or no indication of limitation with food access or changes in diet quality and food intake;
- For scores of 2-4: low food security- reports of reduction in diet quality, with little or indication for reduction in food intake;
- For scores of 5-6: very low food security- Several indications of disruptions with eating patterns reported, in addition to reduction in food intake

Physical Examination

A physical examination and medical history were performed by a trained nurse under the supervision of a physician. Weight and height were obtained in participants wearing light clothing and no shoes utilizing a standard scale calibrated prior to each measurement. Height was measured with the participant's heels touching the base of the vertical board of the stadiometer. The movable headboard was brought to the most superior point on the head with sufficient pressure to compress the hair.

Anthropometrics were also obtained, and body mass index (BMI) was calculated by dividing the weight in kilograms by height in meters squared. Waist and hip circumference was measured using a tape measure. Waist circumference was measured at the narrowest part of the waist between the lowest rib and the iliac crest and the hip circumference at the widest portion of the buttocks. Bioelectrical impedance analysis (BIA) using the Biodynamics body composition analyzer (model BIA-450; Biodynamics Corp., Seattle, WA), determined impedance and calculated body composition. Subjects were measured, lying down, without shoes and socks, and electrodes were placed on the participant's right hand and wrist and right foot and ankle. Blood pressure was measured in the left arm with the elbow flexed to heart level techniques.

Biochemical data and Laboratory Values

Fasting blood samples were drawn for the assessment of fasting glucose and homocysteine levels and sent to a commercial laboratory for analysis. Values on total cholesterol (TC), HDL cholesterol (HDL-C), LDL cholesterol (LDL-C) and triglycerides (TG) were abstracted from the participants' medical records accessed with their written consent.

Cardiovascular Outcomes

MetS was defined using the 5 NCEP ATPI III risk factors.[20] Three or more criteria had to be met to define MetS: (1) fasting serum TGs (≥ 150 mg/dl), (2) abnormal WC (> 40 inches for men and > 35 inches for women), (3) low HDL-C level (< 40 mg/dl for men and < 50 mg/dl for women), (4) high BP (≥ 130/85 mm Hg), or (5) high FG level (≥ 110 mg/dl).

The 10-year risk of CVD was calculated using the FRS proposed by the ATP III.[20] The gender-based formula takes into account age, smoking status, total and HDL cholesterol, and systolic blood pressure to generate the estimated 10-year risk. Individuals with an estimated risk ≥ 10% and MetS were classified as high risk for CVD.

Statistical Analysis

SPSS-22 was used for statistical analysis and $P < 0.05$ was considered significant. MetS was examined in relation to standard and other risk factors. Frequency and descriptive statistics were calculated on all variables. Student's t-test was used to assess differences between the two groups, and chi-square was used for categorical variables.

Results

The demographic, anthropometric and CVD risk factors are presented in Tables 1 and 2. The majority of participants (n = 100) were male (62.0%) and Black (77.0%). Approximately 73.0% of participants had a high school education, with an average monthly income of $472, while approximately 89.0% were currently receiving nutritional assistance with the Supplemental Nutrition Assistance Program (SNAP). Low household food security was reported by 11.0% of participants. A comparison of socio-economic characteristics between the two groups showed no significant differences between those who were receiving counseling by an RD compared to those who did not (Table 1).

Although 76.0% (n = 76) have seen an RD in the past, only 48.0% (n = 48) have seen one in the past 12 months, with almost one-quarter of them (n = 24; 24.0%)

reporting never receiving nutritional services. Of those who were currently seeing an RD, 47.9% visited the Dietitian 4 or more times in a year, 11 only 1 time, and 76 have no nutritional intervention. On average, participants reported that they had been attending lasted 43.7 minutes

Significant differences were seen between the participants who were attending nutritional counseling sessions and those who were not in anthropometric and body composition measurements. Individuals who were seeing an RD had lower BMI (26.0 vs. 28.8; $P = 0.019$), WC measurements (35.5 vs 38.5 inches; $P = 0.003$), and fat mass (46.7 vs. 57.8; $P = 0.032$) (Table 2). Furthermore, 71.2% of participants who had not seen an RD were categorized as overweight, obese, or morbidly obese (Figure 1).

The incidence of MetS was found to be lower and approaching significance in PLWH among participants who were attending nutrition counseling by an RD (18.7% vs. 34.6%, $P = 0.076$) than those who did not have nutritional counseling. PLWH who were seeing an RD had lower values forfewer MetS risk factors compared to those who had not seen an RD. There were several ATP III risk factors that were significantly different between the two groups. HIV-infected persons who were receiving nutritional counseling had lower WC (35.5 vs. 38.5 inches, $P = 0.003$), higher HDL (53.4 vs. 46.7 mg/dL, $P = 0.009$), lower systolic blood pressure (114.8 vs. 127.9 mmHg, $P < 0.001$), lower diastolic blood pressure (75.5 vs. 84.1 mmHg, $P < 0.001$) and lower triglyceride levels (110.8 vs. 168.1, $P < 0.001$) compared to those who did not receive nutritional counseling (Table 2).

Using the FRS, it was determined that only 10.42% of PLWH who were attending nutrition counseling sessions by an RD had a 10-20% risk of developing MI within the next 10 years, compared to the 19.23% among those participants who were not seeing an RD. Risk factors associated with higher FRS among those who were receiving nutritional counseling and that were significantly different included total cholesterol (166.9 vs. 189.2, $P = 0.004$), HDL (53.4 vs. 46.7 mg/dL, $P = 0.009$) and systolic blood pressure (114.8 vs. 127.9 mmHg, $P < 0.001$), respectively (Table 2).

The summary of lipid profiles and other CVD risk factors are shown in Table 2. PLWH who were seeing an RD had significantly better lipid panel values compared to those not seeing an RD; TC (166.9 vs. 189.2 mg/dL; $P = 0.004$), HDL (53.4 vs. 46.7 mg/dL; $P = 0.009$), LDL (93.4 vs. 112.76 mg/dL; $P = 0.003$) and TG (110.8 vs. 168.1 mg/dL; $P < 0.001$). There were no significant difference between the two groups for life-style risk factors of smoking and drinking ($P = 0.332$ and 0.785), respectively. Table 3 shows that the lipid profiles were significantly better among those who had seen an RD compared to those who had not. The test for slope was significant for total cholesterol ($P = 0.002$), HDL ($P = 0.004$), LDL ($P = 0.003$), and triglycerides ($P < 0.001$), indicating a dose-response effect for the RD group.

Discussion

In this study, we investigated whether HIV-infected persons who were attending nutrition counseling by an RD had lower risk for MetS and CVD compared to those not currently seeing an RD. Using ATP III criteria, 27% of participants in this study were estimated to have MetS at the time of their enrollment in the MASH cohort. While the difference was not significant, a greater number of individuals

who were not receiving nutrition counseling by an RD met the criteria for MetS compared to those receiving nutrition counseling by an RD (34.6 vs. 18.7% respectively; $P = 0.076$). Similar to results of other studies, the incidence of MetS in almost one in three individuals in this study was driven by a high rate of abdominal obesity and dyslipidemia.[8,14] However, within our sample we also found a significant difference in both diastolic (114.8 vs. 127.9 mmHg; $P < 0.001$) and systolic blood pressure (114.8 vs. 127.9 mmHg; $P < 0.001$) between those who were receiving nutritional counseling from an RD and those who were not. In contrast to the study by Jacobson et al.[8], blood glucose levels within our sample were found to be within normal limits, therefore, did not contribute to the increase seen in MetS.

Lipid abnormalities are commonly reported in HIV-infected individual receiving ART.[11,13,21] In this sample of HIV-infected persons we found that individuals seeing an RD had significantly better lipid panels than those not seeing an RD. Other studies have shown that dietary intake similar to that of the Mediterranean diet were beneficial in improving lipid profiles and lowering the risk of CVD as measured by the FRS.[22,23] While we did not find a significant difference in the FRS score between those who did and those who did not receive advice from an RD, there was a larger percentage of those who did not see an RD who had a greater risk for developing CVD.

One limitation of this study was the cross-section design of the study which prohibits us from drawing causal conclusions. Lastly, the external validity of the study is also decreased because we used a convenience sample of HIV-positive persons from one county.

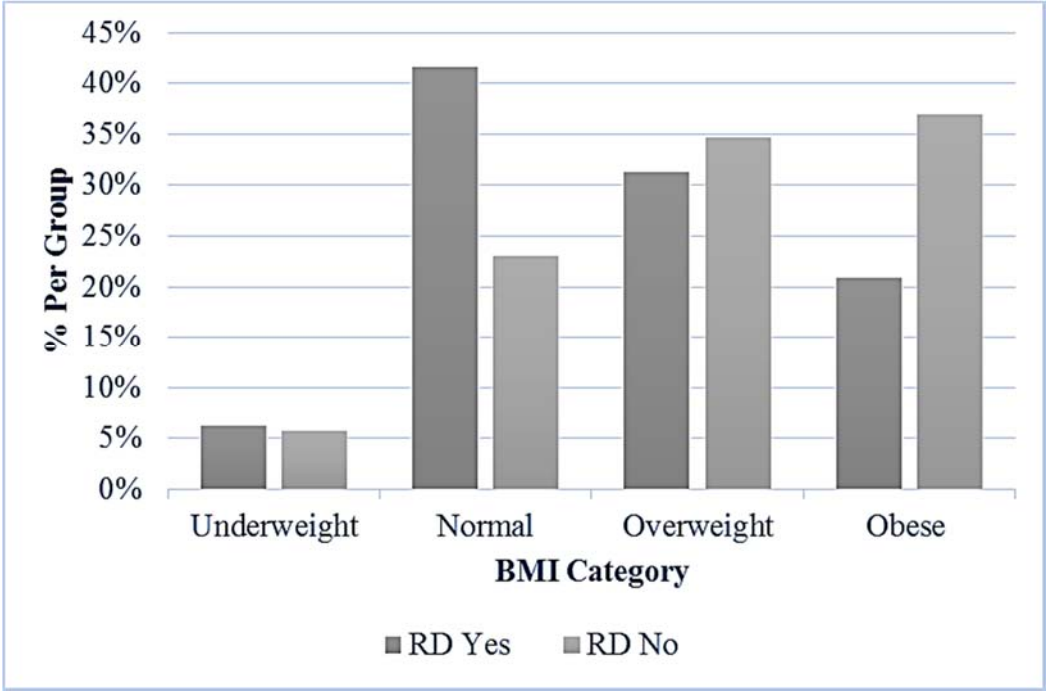
In conclusion, this is the first observational study looking at the impact of dietary counseling by an RD has on CVD risk factors for HIV-infected persons receiving HAART. The group of HIV-positive individuals who were receiving nutrition counseling by an RD had significantly better CVD risk factors compared to those who had not seen an RD in the previous 12-months. The prevalence of MetS in the MASH cohort is lower for those who were seeing an RD than previously reported in the general population (25%) and recently, in HIV-positive cohorts (33%).[5,24] Overall, individuals were seeing an RD had a better lipid panels and a lower estimated risk for CVD. Future research should focus on longitudinal dietary changes specifically designed to improve CVD risk factors.

Table 1: Characteristics of the population.				
	Total (n = 100)	**RD Yes (n = 48)**	**RD No (n = 52)**	***P*-value**
Age, mean (SD)	47.8 (6.8)	47.5 (7.3)	48.1 (6.4)	0.692
Gender (%)				
Male	62.0	58.3	34.6	
Female	38.0	41.7	65.4	0.473
Marital Status (%)				
Single	87.0	89.6	84.6	
Married	13.0	10.4	15.4	0.466
Race/Ethnicity (%)				
White	7.0	10.4	3.8	
Black	77.0	75.0	11.5	
Hispanic	11.0	10.4	78.8	
Other	5.0	4.2	5.8	0.287
Income, mean (SD)	472.3 (474.9)	410.90 (431.5)	528.9 (509.4)	0.216
Education, mean (SD)	11.5 (2.7)	11.23 (3.4)	11.8 (1.9)	0.297
Food Security (%)	89.0	90.4	87.5	0.914
SNAP (%)	89.0	83.0	94.0	0.013*
*Statistically significant $P < 0.05$				

Table 2: Cardiovascular risk factors.				
	Total (n = 100)	**RD Yes (n = 48)**	**RD No (n = 52)**	***P*-value**
Lifestyle Risk Factors				
Smoking (%)	66.0	70.8	61.6	0.332
Alcohol Consumption (%)	59.0	60.4	57.7	0.785
Cocaine/Crack (%)	26.0	33.3	19.2	0.110
Overall Urine Toxicology %	63.0	68.8	57.7	0.257
Anthropometrics				
BMI (kg/m^2), mean (SD)	27.4 (5.9)	26.0 (5.2)	28.75 (6.2)	0.019**
Waist Circumference (inch), mean (SD)*	37.1 (5.1)	35.5 (4.7)	38.50 (5.1)	0.003**
Waist:Hip (cm), mean (SD)	0.9 (0.1)	0.9 (0.1)	0.93 (0.1)	0.177
Body Composition				
Fat Mass (%), mean (SD)	52.5 (25.8)	46.7 (23.0)	57.8 (27.2)	0.032**
Fat %, mean (SD)	28.4 (10.5)	27.0 (10.2)	29.7 (10.6)	0.187
BCM, mean (SD)	63.6 (15.1)	60.9 (12.9)	66.1 (16.6)	0.082
BCM %, mean (SD)	36.7 (8.9)	27.0 (10.2)	29.7 (10.6)	0.934
Lipid Panel				
Total Cholesterol, mgl/dL, mean (SD)	178.5 (39.0)	166.85 (36.95)	189.23 (38.00)	0.004**
HDL, mgl/dL, mean (SD)*	49.9 (12.9)	53.40 (13.47)	46.71 (11.56)	0.009**
LDL, mg/dL, mean (SD)	103.4 (33.4)	93.40 (31.08)	112.76 (32.99)	0.003**
Triglycerides, mg/dL, mean (SD)*	140.6 (75.3)	110.79 (57.62)	168.12 (79.64)	< 0.001**
Other				
Fasting Blood Glucose mg/dL, mean (SD)*	101.3 (32.5)	101.2 (30.6)	101.3 (34.5)	0.990
Homocysteine mg/dL, mean (SD)	10.1 (3.6)	9.5 (2.4)	10.7 (4.3)	0.083
CVD Risk Factors				
Framingham risk, mean (SD)	4.6 (4.8)	4.1 (4.6)	5.0 (4.9)	0.307
Metabolic Syndrome (%)	27.0	18.7	34.6	0.076
Systolic BP mmHg, mean (SD)*	121.6 (18.2)	114.8 (15.4)	127.9 (18.5)	< 0.001**
Diastolic BP mmHg, mean (SD)*	80.0 (11.8)	75.5 (9.4)	84.1 (12.4)	< 0.001**
*MetS Risk Factor **Statistically significant P < 0.05				

Table 3: Linear regression for CVD risks between groups.			
	β	**95% Confidence**	***P*-value**
Total Cholesterol mg/dL	-23.896	-38.925, -8.868	0.002*
HDL mg/dL	7.289	2.359, 12.220	0.004*
LDL mg/dL	-20.330	-33.573, -7.088	0.003*
Triglycerides mg/dL	-57.293	-85.605, -28.981	< 0.001*
Homocysteine mg/dL	-1.423	-2.865, 0.019	0.053
Diastolic BP mg/dL	-8.646	-13.304, -3.989	< 0.001*
Systolic BP mg/dL	-14.056	-21.204, -6.907	< 0.001*
*Significance *P*-value < 0.05 **Controlled for age, gender, education, income, marriage, AUDIT score, urine toxicity ***Each model ran independent			

Figure 1: Comparison of BMI by category per group



Legend: The only significant difference between the two groups is that those who consulted an RD, have a significantly higher proportion of participants within the normal range (48% vs. 25% in the group without RD counseling, *P*=0.017).

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CHAPTER VII: SUMMARY AND CONCLUSIONS

Findings from this study indicate that counseling by a Registered Dietitian (RD) is associated with better health outcomes among people living with HIV (PLWH). However, due to limited resources and education, there are multiple barriers that impede access to nutritional counseling and adherence to nutritional therapy, such as lack of referrals or lack of knowledge. Furthermore, the high percentage of individuals who listed lack of referral to services as a barrier is a concern that needs to be addressed. Medical and ancillary personnel need to be educated on the benefits of nutritional counseling to promote referrals to these services and ensure that their patients are aware of these benefits, the availability of the services, and their importance for PLWH. This study identified the barriers that PLWH recognized as impeding their participation in nutritional counseling and improving their nutritional intake. Some of the identified barriers can be overcome with education. Healthcare and ancillary professionals play an important role in ensuring that their HIV-positive patients are educated on the benefits of dietary counseling to improve their nutritional status, delay disease progression and prevent the long-term effects of the antiretroviral treatment (ART). Moreover, it's important that these health professionals inform PLWH about the various nutritional services offered in their treatment clinics and their community, and provide the necessary referrals. Our data suggest that knowledge is critical to remove barriers and for the success of nutritional services in achieving beneficial outcomes. Most of the barriers identified can be removed by providing transportation to patients, improving education on nutritional services for PLWH and their healthcare professionals and establishing regular channels of communication with patients to remind them of their appointments.

The majority of the participants were considered food secure, however, there is still concern about the adequacy of their intakes to meet their dietary needs. In general, we found that this population of PLWH has poor dietary intake and nutritional status, but those consulting an RD had significantly improved dietary intakes and nutritional parameters than those who were not. We also found a high rate of substance abuse, although there were no significant differences between those who consulted an RD and those who did not, probably because the detoxification programs in our recruiting clinics offer the services of an RD. The increased risk of food insecurity and malnutrition that drug users face is often due to supporting their habits rather than buying food.[1]

PLWH are also at increased risk of CVD because of the chronic use of ART, and especially in our cohort, due to frequent substance abuse.[2] Consulting an RD was associated with reduced rate of dyslipidemias and other nutrition-related risk factors for CVD, which is of importance in this population already at high risk of morbidity and mortality from CVD.

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CHAPTER VIII: STRENGTHS AND LIMITATIONS

This research provides valuable information on barriers for access and delivery of nutritional services for PLWH. This study is the first one to identify barriers to receiving nutritional counseling with a Registered Dietitian (RD) and compare the nutritional and health outcomes among participants with HIV who do or do not receive this service.

The results from this study may be used to improve access to nutritional services by implementing strategies that minimize the most prevalent barriers towards receiving nutritional counseling by an RD, and promoting referral from health professionals. In addition, our study is also the first observational study to monitor the health outcomes, dietary intake, nutritional status, and nutrition-related co-morbidities among participants who receive nutritional counseling by an RD. This study provides preliminary data for future studies on how to improve current programs and develop effective intervention strategies. Participants from this study were recruited from the Miami Adult Studies on HIV (MASH) cohort, which not only provided an ample sample to recruit from, but also had an extensive and longitudinal repository of data that contained many of the variables used for this study.

Several limitations of this study are acknowledged and presented briefly below. This was an observational study; thus, only associations between the variable of interest can be assumed. In addition, the study described and compared the Alternate Healthy Eating Index (AHEI) between PLWH who did or did not receive nutrition counseling from an RD using 24-hour recalls to obtain dietary information. While 24-hour recalls are considered adequate for providing information on dietary intake, they were not intended to be used with the AHEI. In addition, the study sample in this investigation

was a convenience sample obtained by recruiting consecutive 130 participants from the MASH cohort, rather than a representative sample of the population. Furthermore, because study participants were recruited from one location, the results may not be generalizable to other HIV seropositive people in the United States or around the world.

CHAPTER IX: FUTURE RESEARCH

A longitudinal, randomized controlled clinical trial of nutritional counseling for people living with HIV (PLWH) will be developed using the findings of this dissertation as preliminary data. This type of trial is needed to monitor changes over time to determine if a causal relationship exists between nutritional counseling and diet-related outcomes, such as improvement in quality and adequacy of diet, preventing or ameliorating morbidity, and increasing food security and quality of life.

The features and frequency of the intervention will be determined by a needs assessment, and the delivery of the education and nutritional recommendations will be shaped by psychological techniques such as Motivational Interviewing to establish rapport and influence change, and framed by Theories of Behavioral Change. In addition, nutrition intervention studies need to be designed specifically for those of low socioeconomic status, homeless and drug users, all of which are prevalent among PLWH.

This study already provides initial data to support further research that investigates the association between substance use and dietary intake. Future studies will also consider the longitudinal effects of substance abuse on the nutritional status of PLWH. More frequent substance use and longer duration of substance use may be associated with greater effects on dietary intake that will impact nutritional status and HIV disease progression.

Findings from our study confirm that nutritional counseling appears to be beneficial for PLWH, yet the most commonly identified barrier for those not receiving services was lack of referral or knowledge about the available programs. Intervention studies designed to increase the awareness of the benefits of nutritional services in the

HIV community are needed. Adequate resources are needed to address these barriers and provide education to both professionals making referrals and the HIV community. Future studies should also investigate the cost/benefit of nutritional interventions in preventing morbidity, disability and increasing quality of life. In addition, the periodic surveying of nutritional services programs would be beneficial to determine the effectiveness of that specific program to satisfy both educational needs and nutritional benefits.

Table 1: HIV, Malnutrition and Nutritional Status.			
Author, Year, Study Design	***Study Purpose***	***Study Populations***	***Outcome***
Sharkey JS, Sharkey KA, Sutherland LR, et al., 1992[1] *Case-Controlled Pilot Study*	Evaluate the relationship between dietary intake (7-day weighted dietary intake) and nutritional status (body mass index (BMI), midarm circumference (MAC) and serum protein and albumin) and determine how they relate to disease progression using measurements of CD4 counts.	44 HIV-positive homosexual adult males	As CD4 count decreased a decline was also seen in BMI, MAC, energy intake, serum protein and albumin levels.
Khalili H, Soudkakhsh A, Hajiabdolbaghi M, et al., 2008[2] *Cross-sectional study*	Evaluate the nutritional status of newly diagnose HIV-infected individuals and compare serum zinc and selenium levels in an uninfected healthy sample.	100 HIV newly infected and 100 uninfected controls from Iran	Severe, moderate and mild malnutrition were detected in 15%, 38% and 24% of newly diagnosed individuals respectively. Compared with uninfected control group, serum zinc and selenium were significantly lower among HIV-infected ($P = 0.01$ and $P = 0.02$ respectively).
Liu E, Spiegelman D, Semu H, et al., 2011[3] *Observational study*	Investigate the associations between nutritional status, (body mass index (BMI), middle upper arm circumference (MUAC), and hemoglobin (Hgb) at ART initiation, and death within the first 3 months of initiating therapy.	18,271 HIV-infected adults initiating ART in Tanzania	Lower BMI, MUAC, and Hgb concentrations were strongly associated with a higher risk of death within 3 months. The highest risk was observed among patients with BMI <17 kg/m^2. Poor nutritional status at ART initiation and in the first 3 months of ART is strong independent predictors of mortality.
Tang AM, Forrester J,Spiegelman D, et al., 2002[4] *Observational study*	Determine if wasting is associated with decreased survival in patients receiving HAART and which parameter between weight, fat-free mass (FFM), body cell mass (BCM), or fat mass (FM) is associated with mortality.	678 HIV-positive individuals from the Nutrition for Healthy Living cohort	Weight loss was the strongest predictor of mortality. A weight loss of ≥ 10% from baseline was associated with a 4 to 6-fold increase in mortality compared to maintaining or gaining weight.

Hendricks KM, Willis K, Houser R, et al., 2006[5] *Cross- sectional study*	Describe the prevalence of obesity among a cohort of HIV-positive individuals and to determine the differences in dietary intake among those subjects who are normal weight, overweight, and obese.	321 HIV-positive adults from the Nutrition for Healthy Living cohort.	13% males and 29% females were obese. Energy intake per kg decreased as BMI decreased in both genders (P <0.05). Mean total fat and saturated fat intakes were above recommendations for both sexes in all BMI categories, while dietary fiber intake decreased as BMI increased. Individuals in all BMI groups reported micronutrient intakes below the DRI's.
Lazzaretti RK, Kuhmmer R, Sprinz E, et al., 2012[6] *Randomized Clinical Trial*	Evaluate the efficacy of dietary intervention on blood lips in HIV-infected patients initiating HAART.	83 HIV-infected patients who were HAART naïve	Diet intervention resulted in a reduction in the intake of percent of fat (31% to 21%) and in TG (135 to 101 mg/dl). While the control group had an increase in plasma cholesterol (151 to 190 mg/dl), LDL (85 to 106 mg/dl), and TG (134 to 160 mg/dl). At 1-year f/u 21% of diet intervention group had dyslipidemia compared to the 68% in the control group.
Tsiodras S, Poulia KA, Yannakoulia M, et al., 2009[7] Cross-sectional *study*	Investigate the effect of adherence to a Mediterranean-style diet on metabolic aspects of HARRT induced MetS (fat distribution, insulin resistance, dyslipidemia).	227 HIV-infected subjects from a research clinic in Israel	Dietary adherence was positively correlated with HDL levels (P=.01). Inverse associations were found between insulin resistance (P=.03) and fat distribution (P=.02) with dietary intake. Mediterranean diet shows metabolic improvements that can be maintained long term.

Table 2: HIV and Quality of Diet.			
Author, Year, Study Design	***Study Purpose***	***Study Populations***	***Outcome***
McDermott AY, Shevitz A, Must A, et al. 2003[122] *Quasi-experimental design*	Determine the effectiveness of intensive dietary recommendations plus an oral nutrition supplement on energy and protein intake, weight, and fat-free mass (FFM).	39 HIV-infected persons with documented wasting receiving nutrition intervention and 56 controls	At baseline there were many misconceptions about nutrition and HIV. The customized nutrition intervention resulted in marked improvements in dietary intake, weight, and body composition. A reversal in unintentional weight loss was seen in individuals regardless of disease progression or medication compilations.
Wang EA, McGinnis KA, Fiellin DA, et al., 2011[67] *Cross-sectional study*	Examine the impact of food insecurity on HIV disease outcomes among HIV-infected patients receiving ART.	2353 HIV-infected participants from the Veterans Aging Cohort Study	24% of veterans were food insecure. A correlation between food insecurity and unsuppressed HIV-1 RNA was found, with no association between ART adherence and BMI. Food insecurity was not independently associated with low CD4 counts.
Weiser SD, Fernandes K, Brandson EK, et al., 2009[68] *Longitudinal cohort study*	Assess the associations between food insecurity, BMI, and mortality in HIV-infected persons on ART.	1119 HIV-infected individuals initiating ART in Vancouver	48% were food insecure and 14% were underweight (BMI <18.5). 14% died from non-accidental deaths, with food insecure and underweight individuals being twice as likely to die. A trend towards increased mortality risk was observed among food insecure and not underweight individuals. However, underweight, food secure individuals were not more likely to die.
Chiuve SE, Fung TT, Rimm EB, et al., 2012[80] *Cross-sectional study*	To assess the association between the AHEI-2010 and the HEI-2005 and risk of major chronic disease.	71,495 women from the Nurses' Health Study and 41,029 men from the Health Professionals Follow-Up Study	Comparison of the two measurements shows that the AHEI-2010 had a stronger association with coronary heart disease and diabetes ($P = 0.002$ and < 0.001, respectively). While both measurements had similar associations with risk of stroke and cancer. The AHEI includes additional dietary information that is usual when determining risk of major chronic disease.

Akbaraly TN, Ferrie J, Berr C, et al., 2011[81] *Longitudinal cohort study*	Examine the association between adherence to the AHEI and mortality risk and investigate the AHEI components.	7319 participants from the Whitehall II Study.	Participants with AHEI scores in the top 3rd cortile had >40% lower mortality from CVD and 25% lower all-cause mortality. Consumption of nuts and soy and moderate alcohol intake were the most significant contributors to the decrease seen in mortality.
Hendricks KM, Mwanburi DM, Newby PK, et al. 2008[84] *Longitudinal cohort study*	Assessed the association between dietary patterns and change in body mass index (BMI), CD4 count, and viral load (VL).	348 HIV-positive adult male with a BMI >or= 20.5	3 dietary patterns were identified: juice and soda; fast food and fruit drinks; and fruit, vegetable, and low-fat dairy. The fast food and fruit drinks group had the lowest fiber intake, highest VL, and lowest CD4 count and had a lower income. Subjects in the fruit, vegetable, and low-fat dairy diet group had higher intakes of fiber, and micronutrients and the highest BMI and CD4 count. Individuals with juice and soda group had higher energy intakes and lowest BMI.
Segal-Isaacson CJ, Tobin JN, Weiss SM, et al., 2006[30] *Quasi-experimental design*	Determine whether nutrition education can succeed in improving long-term dietary patterns.	466 disadvantaged HIV-infected women	Nutrition education led to significant improvement in dietary patterns for all participants even after 18 months after intervention. Improvements were seen in the consumption of high fat and high sugar foods.

Table 3: HIV, Malnutrition and Substance Abuse (Alcohol and Illicit Drugs).			
Author, Year, Study Design	***Study Purpose***	***Study Populations***	***Outcome***
Quach LA, Wanke CA, Schmid CH, et al., 2008[88] *Cross-Sectional Study*	Examine the relationship between BMI and several covariates in drug users vs. non-users	562 HIV-positive people enrolled in the NFHL	The adjusted BMI of cocaine users was 1.4 kg/m^2 less than that of non-users ($P = 0.02$). While the BMI seen with other types of drugs did not significantly change.
Campa A, Yang Z, Lai S, et al., 2005[63] *Observational study*	Document the prevalence of HIV-related wasting and of associated factors, including food intake, viral load, quality of life, and HAART use.	119 HIV-infected homeless drug users from Miami-Dade County	The prevalence of HIV-related wasting was 17.6%. A greater number of participants experiencing wasting received HAART, however, their HIV RNA levels were more than twice as high (166,689 copies/mL) compared to those not experience wasting (149,080 copies/mL). Wasting was related to heavy alcohol drinking and cocaine use.
Forrester JE, Tucker KL, Gorbach SL, et al., 2004[97] *Prospective cohort study*	Determine the relationship between drug abuse and dietary intake in Hispanics with and without HIV.	131 HIV-positive individuals, both drug abusers and non-users and 81 HIV-negative drug abusers.	HIV-positive abusers had BMI's within the normal range however, they were significantly lower compared to the HIV-positive non-users (25.2 vs. 27.0). However, reported dietary intake was similar between the groups for energy, fat, and fiber.

Table 4: HIV and Barriers to Nutritional and Health Interventions.			
Author, Year, Study Design	***Study Purpose***	***Study Populations***	***Outcome***
Brunner RL, Larson TA, Scott BJ, et al., 2001[106] *Qualitative*	Evaluation of nutritional services.	16 HIV-infected individuals enrolled in nutrition program for 1 year	Individuals believed nutrition was important in the HIV health (75%). While participants were satisfied with the program, there were barriers that they identified to participation in nutritional services. Difficulty keeping appointments, concern about confidentiality, multiple locations for care and cost of care were the top listed barriers. However, individuals stated that they would still refer other to the program (100%).
Kalichman SC, Catz S, Ramachandran B, et al., 1999[113] *Observational*	Examination of association between education literacy and barriers to care.	138 HIV-positive African Americans on ART	Lower education and literacy levels were identified as barriers to HIV-related health care treatment. 29% of participants had <12 years of education or were functionally illiterate. Those less educated were less adherent to medication regiments ($P <$ 0.05) do to confusion about the regiment.
Roberts KJ, 2000[109] *Qualitative*	Describe the barriers that HIV+ persons face adhering to ART.	28 HIV-positive patients from the San Francisco AIDS Program	5 main barriers towards ART adherence were identified 1) forgetfulness, 2) social/physical environment, 3) complexity of regimens, 4) medication side effects, & 5) inadequate patient knowledge.

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PRESENTATIONS

Fleetwood C, Campa A, Martinez SS, Stewart T, Seminario L, Gracia D, Baum MK. Nutritional Intervention Decreases Risk of Metabolic Syndrome and Improves Quality of Diet. Experimental Biology 2015 Conference, Boston, Massachusetts, March 28-Apri 1, 2015.