EFFECT OF FOOD BASED NUTRITION INTERVENTION; PROLCARMIV ON MANAGEMENT OF NONCOMMUNICABLE DISEASES AMONG PEOPLE LIVING WITH HIV IN BUSIA, KENYA

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A Thesis Submitted to the School of Public Health, Biomedical Sciences and Technology in Partial Fulfilment for the Requirements of The Award of Doctor of Philosophy in Medical Dietetics of Masinde Muliro University of Science and Technology

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DECLARATION

This thesis is my original work prepared with no other than the indicated sources and support and has not been presented elsewhere for award of a degree.

Sign……. Date……

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CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance of Masinde Muliro University of Science and Technology a research proposal entitled **"Effect of food based nutrition intervention – PROLCARMIV on management of Non Communicable Diseases among people living with HIV in Busia, Kenya"**

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ABSTRACT

Good Nutrition optimizes benefits of ART and increases treatment adherence, both prolongs lives of PLHIV (NASCOP, 2014), without proper care and management it exposes them to non-communicable diseases (NCDs). Key objective; To determine the effect of food-based nutrition intervention on the management of NCDs among PLHIV in Busia. Design was experimental using randomized control trial approach. Control group- 30 subjects fed on Plumpy 'nut while treatment group – 30 subjects fed on Power Porridge (PROLCARMIV), for 60 days. Subjects purposively selected from the Comprehensive Care Clinic (CCC) in Busia County referral hospital- Kenya, further randomly selected using simple random sampling, assigned equally to each group. Data collected using a structured questionnaire analyzed using Social Package for Statistical Sciences version 26. Prevalence of NCDS; 75.5% hypertension; 15.6% Diabetes and 8.9% heart disease; post-intervention BMI for intervention group increased; Laboratory analyses; Hb post–intervention results; mean levels were higher in intervention group (M=13.62, SD=2.69) p-value = 0.487 compared to control group (12.69, SD=1.24), p value= 0.471. RBS were higher in control group (5.96, SD=1.70), p value= <0.001, intervention group (M=5.79, SD=1.02), p-value = <0.001. Post-intervention liver function test; TB, AST, and ALT showed higher SD indicating variability. Lipid profile; showed TC mean (4.39 (0.95) for control group; a mean 3.78(0.94) intervention group: p=0.017; HDL -control group mean 1.58(0.57): 1.14 (0.53) intervention group p=0.036: TG - control group mean 1.50 (0.50): intervention group p= 0.017: mean 1.14: (0.46): LDL mean 2.26 (0.66) control group: 1.43 (0.42): intervention group p= 0.041: all exhibited significant decreases. Kidney function tests; no significant differences between the two groups. Conclusion; Compliance for PROLCARMIV; 82.5%, attracting uptake of CCC services. PROLCARMIV can manage NCDs among PLHIV, answering the alternative hypothesis, this would inform Policy.

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LIST OF ACRONYMS AND ABBREVIATIONS

ALB	Albumin;
ALT	Alanine Aminotransferase
AMARANTH	Amaranthus Dubius
ARVs	Anti- retroviral
AST	Aspartate Aminotransferase
ALP	Alkaline Phosphatase
BMI	Body Mass Index
BUN	Blood Urea Nitrogen
CCC	Comprehensive Care Clinics / Centers
Cl	Chloride
CHVs	Community Health Volunteers
CONSORT	Consolidated Standard of Reporting trials
DB	Direct Bilirubin
DM	Diabetes mellitus
FMSC	Finger Millet Seed Coat
HTN	Hypertension
HBM	Health Behaviour Model
Hb's	Haemoglobin Levels
HiCN	Hemiglobincyanide
HDL	High-Density Lipoprotein;
K	Potassium
KDHS	Kenya Demographic and Health Survey
KUNDE	Vigna Unguiculata (L) Walp
LDL	Low density Lipoprotein
GGT	Gamma glutamly Transferase
GFR	Glomerular Filtration Rate
MF	Millet flour
MOH	Ministry of Health
NGO's	Non-governmental Organizations
Na	Sodium
PF	Pumpkin Flour

TB	Total Bilirubin
TC	Total Cholesterol
TG	Triglyceride
TP	Total Protein
PPP	Prolcarmiv Power Porridge
NCDs	Non – Communicable Diseases
PLHIV	People Living with HIV
RDA	Recommended Daily Allowance
SD	Standard Deviation
SF	Soya Flour
SG	Specific Gravity
SP	Sulfadoxine Pyrimethamine
SSA	Sub-Sahara Africa
SPSS	Statistical Package for Social Surveys
WHO	World Health Organization
KHSSP	Kenya Heath Sector Strategic and Investment Plan.
UNAIDS	The Joint United Nations Programme on HIV/AIDS

OPERATIONAL DEFINITION OF TERMS

Active Control	In this study it is an investigational food compared to the treatment Food that demonstrates equal effectiveness
Anthropometrical measurements	In this study height and weight were taken and BMI was calculated from the height and weight.
Body Mass Index (BMI)	Is a measure of nutritional status used to judge the level of undernourishment or over nourishment.
Prolcarmiv	It a power porridge. Meaning it is composed of Proteins, Lipids, Carbohydrates, Minerals and Vitamins; this was feed to the Treatment group.
Power Porridge	Same as Prolcarmiv
Plumbynut	Standard Food Product Composed of energy, mineral, vitamins and carbohydrates
Control Group	Are PLHIV with NCDs included in the study who consumed the Standard Food
Treatment Group	Are PLHIV with NCDs included in the study who consumed the Power Porridge
RCT	Randomized control Trial are prospective studies that measure the effectiveness of a new intervention or treatment
Opportunistic Infection	An infection that exhibits higher frequency or greater severity in individuals with compromised immune systems, such as those with HIV or undergoing chemotherapy, compared to others with robust
Malnutrition	Is a state of nutrition where BMI is <18.5
HIV	The retrovirus under consideration is capable of infecting immune system cells, leading to the destruction or impairment of their
NCD	A disease that is not transmissible directly from one person to another, as in this study Hypertension, Diabetes and Heart Disease.
Wash out period	A washout period refers to a designated interval of time that occurs between the conclusion of one phase and the commencement of the subsequent phase, during which there is an absence of any manipulation or independent variable. In this study it was administration of SP Malaria drugs and

Quality of Life The concept of leading a life with reduced burden of sickness, specifically in relation to daily functioning, is highly valued by

CHAPTER ONE

INTRODUCTION

1.1 Background Information of the study

Non-communicable diseases (NCDs) are responsible for the mortality of around 41 million individuals annually, accounting for approximately 74% of the total global deaths. According to the World Health Organization (WHO, 2022), a staggering number of 17 million individuals succumb to non-communicable diseases (NCDs) annually, prior to reaching the age of 70. It is noteworthy that a significant majority, specifically 86%, of these untimely fatalities transpire within low- and middle-income nations. According to the National AIDS Control Council (NACC, 2017), the 7th edition of the AIDS in Kenya publication reveals that the HIV prevalence rate among adult women is eight percent, while among adult men it is four percent. According to a study conducted by Achwoka, Waruru, Chen, et al. (2019), which involved a nationally representative sample, it was shown that people living with HIV (PLHIV) in Kenya exhibit a substantial occurrence of non-communicable disease (NCD) diagnoses. The objective of this research was to assess the prevalence of non-communicable diseases (NCDs) among people living with HIV (PLHIV) who were receiving HIV therapy in Kenya during the period from 2003 to 2013. The majority of surveys conducted in Sub-Saharan Africa (SSA) to evaluate the impact of non-communicable diseases (NCDs) on people living with HIV (PLHIV) have employed cross-sectional or longitudinal methodologies using data collected at the facility level (Kagaruki et al., 2014; Edwards et al., 2015). Furthermore, the samples included in this study have been of a lesser size and

have exhibited even less representativeness. According to Farahani et al. (2014), prior research on the treatment outcomes of HIV in sub-Saharan Africa (SSA) has not adequately examined the co-occurrence of non-communicable diseases (NCDs) among people living with HIV (PLHIV). The recognition of the risk associated with the development of chronic non-communicable diseases is growing within the population of individuals living with HIV, which is considered a significant concern in the field of public health. The demographic characteristics of people living with HIV (PLHIV) who are receiving antiretroviral therapy (ART) are undergoing significant transformations, leading to significant ramifications for the provision of clinical care and management in both urban and rural settings. The adoption of a suitable dietary regimen has the potential to enhance the quality of life (QoL) for individuals affected by HIV. According to Fathima et al. (2022), inadequate nutrition among individuals living with HIV (PLHIV) accelerates the progression of the disease, heightens the incidence of illness, and reduces the overall duration of survival. The increase in energy requirements among people living with HIV (PLHIV) has been well-documented (NASCOP, 2014), thus necessitating the adoption of a balanced and diverse dietary approach. Research has also indicated an upward trend in the prevalence of non-communicable diseases (NCDs) among individuals living with HIV (PLHIV) in comparison to those without HIV infection. This finding has significant ramifications for the provision of healthcare services, support systems, and clinical interventions. According to Mathebula et al. (2020), This issue is particularly noticeable in emerging nations, where there is a growing prominence of dietary and lifestyle risk factors linked to non-communicable diseases (NCDs). According to the study conducted by Chhoun et al. (2017), Both HIV and NCD are medical illnesses that require effective management through a comprehensive approach that encompasses Food, Nutrition, and

Dietetics. This study underscores the importance of utilizing locally accessible food resources, doing laboratory and clinical monitoring, promoting behavioral modifications, and providing support to ensure adherence to treatment. The objective of incorporating a plant-based nutrition intervention, specifically PROLCARMIV, in this study was to provide nutritional benefits to the participants. PROLCARMIV is a product that contains essential components such as fiber, proteins, lipids, carbohydrates, minerals, and vitamins. Laboratory analysis conducted after conducting lipid profile tests indicated an increase in Hb levels and a decrease in levels of "bad fat." These findings are consistent with other investigations conducted by Jafari et al. (2018). Chen Z, et al. (2021). The studies conducted by Baden MY et al. (2021) and Romanos-Nanclares A et al. (2021) are

cademic significance. Each of the aforementioned research examined the advantages of Plant-based diets across cohorts and medical conditions, without employing a randomized controlled trial (RCT) methodology. The study conducted by Steven Y Hong et al. focused on the development of a nutrient-dense food supplement for HIV-infected women in rural Kenya, employing both qualitative and quantitative research methodologies. However, it is important to note that the study did not specifically target non-communicable diseases (NCDs). The study conducted by Elizabeth K. (2009) examined the food consumption patterns and nutritional status of individuals living with HIV/AIDS (PLHIV) in Thika and Bungoma Districts, Kenya. However, it is important to note that this study did not specifically focus on non-communicable diseases (NCDs).

Several technologies and systems utilized in the provision of HIV care can be modified to effectively prevent and manage certain prominent non-communicable diseases (NCDs). It is imperative to adopt an integrated approach to address the co-occurrence of NCDs and HIV, as this will facilitate the management of NCD comorbidities. According to a study conducted

by Leung et al. in 2016, Healthcare expenses for non-communicable diseases (NCDs) deplete household resources rapidly in situations with limited resources. The high expenses associated with non-communicable diseases (NCDs), which encompass both prolonged and costly treatment as well as the loss of primary income earners, result in a significant number of individuals being pushed into poverty on a yearly basis, hence impeding socioeconomic progress. Insufficient provision of nutritional guidance, coupled with challenges related to food availability and access, might impede the successful implementation of Antiretroviral Therapy (ART) among individuals living with HIV (PLHIV). Consequently, this can result in diminished overall well-being, as well as suboptimal nutritional health for this population.

The four primary non-communicable diseases (NCDs) encompass cardiovascular illnesses, malignancies, diabetes, and chronic lung diseases. Non-communicable diseases (NCDs) exhibit a disproportionate impact on individuals residing in low- and middle-income nations, wherein a significant majority of global NCD-related mortalities, amounting to 32 million fatalities, transpire. The prevalence of non-communicable diseases in Sub-Saharan Africa is on the rise. Several studies conducted in Africa have reported a significant prevalence of hypertension, obesity, and hypercholesterolemia among individuals infected with the Human Immunodeficiency Virus (HIV) who are undergoing antiretroviral therapy (Divala et al., 2016). According to Bloomfield et al. (2015), epidemiological research have indicated a rising prevalence and incidence of four primary risk factors for cardiovascular disease: hypertension, hyperglycemia, dyslipidemia, and obesity. In a study conducted by Rooyen et al. (2014), the authors examined the relationship between cardio metabolic markers and the identification of cardiovascular disease risk in black South Africans living with HIV (PLHIV). The findings of the study suggested that the implementation of

antiretroviral medication within the PLHIV community has resulted in notable enhancements in both quality of life and life expectancy. However, it should be noted that engaging in such behavior also exposes individuals to many risk factors associated with the development of obesity, diabetes mellitus, and cardiovascular disease. This has been highlighted by Nsagha et al. (2015), who have discussed the potential health consequences of these risk factors. Additionally, it has been estimated that there is an increase in non-HIV related mortality, with a reported figure of 33.3 million, as shown by Schouten et al. (2014).

Freiberg and Kraemer (2010) have observed that individuals living with HIV commonly exhibit behavioral risk factors associated with non-communicable diseases (NCDs). Furthermore, it is widely acknowledged that advancing age, a familial predisposition, urban living, excessive weight or obesity, and a sedentary lifestyle are established risk factors associated with the development of diabetes. In addition, individuals living with HIV (PLHIV) may encounter heightened susceptibility to diabetes due to many risk factors, such as inflammation. This inflammatory response can have both direct and indirect impacts on the hormonal regulation of insulin sensitivity (Alencastro et al., 2011). Furthermore, it has been observed that the use of specific antiretroviral medications, such as Atazanavir, Rotanavir, and Tenofovir Disoproxil - fumarate, may lead to changes in the distribution of body fat, dyslipidemia, obesity, elevated cholesterol levels, dysglycemia, diabetes, and an increased susceptibility to cardio metabolic diseases. This association has been demonstrated to be more pronounced with higher cumulative exposure to these medications (Tesfaye et al., 2014).

The present study aimed to expand upon previous research by implementing an intervention that specifically targets non-communicable diseases (NCDs) among people living with HIV (PLHIV). This intervention utilized a unique method, employing a food-based nutrition intervention. Notably, this study represents the first of its kind conducted in Kenya.

According to a study conducted by Booysen (2008), HIV serves as a catalyst for poverty. The research findings suggest that, alongside the conventional factors that contribute to poverty, the impact of HIV and AIDS-related illness and death on economic mobility can lead households into a state of persistent poverty. A significant proportion of individuals living in poverty in Africa are women, who frequently assume the role of household heads within the most impoverished homes. Another demographic, namely children living on the streets, have significantly diminished welfare, obtain inadequate education compared to their peers, and face heightened exposure to health risks, involvement in prostitution, drug misuse, HIV infection, and criminal activities. The study will examine the demographic and socio-economic characteristics of patients in order to understand the potential impact of the rapid increase in non-communicable diseases (NCDs) on poverty reduction measures in low-income countries. This rise in NCDs is expected to hinder these activities by raising household expenses related to healthcare.

According to a report published by the Joint United Nations Programme on HIV/AIDS (UNAIDS, 2018), Kenya ranks sixth globally in terms of the magnitude of individuals affected by HIV. Furthermore, HIV remains a prominent contributor to adult

morbidity and mortality in the country. In contrast, it is worth noting that Non-Communicable Diseases (NCDs) are responsible for an annual mortality rate of 182 per 100,000 individuals, resulting in the loss of 12,651 healthy years per 100,000 population on a yearly basis (World Health Organization, 2013). Kenya has witnessed a growing prevalence of non-communicable diseases connected to dietary patterns, particularly in urban regions, as indicated by the Kenya Demographic and Health Survey of 2022. An urgent response is required to effectively address the burden of non-communicable diseases, particularly among those living with HIV.

At the end of 2017, there were 36.9 million [31.1–43.9 million] people living with HIV worldwide; of these, 1.8 million were minors under the age of 15 (WHO, 2017). As of 2017, the proportion of individuals living with HIV varied across different regions of Asia and the Pacific, Eastern and Southern Africa, Western and Central Europe, and North America: 19.6 million (53 percent), 6.1 million (16 percent), 5.2 million (14 percent), and 2.2 million (6 percent) (UNAIDS, 2017).

The national prevalence of HIV among adults aged 15-64 years in Kenya was estimated to be 4.9% in 2018 (KENPHIA, 2018). This equates to 1.3 million adults living with HIV in Kenya (95% CI: 1.2-1.4 million). In urban areas, the prevalence of HIV was 4.7% (95% CI: 4.1%-5.3%), while in rural areas, it was 5.0% (95% CI: 4.5%-5.5%). The report identifies the following counties as having the highest prevalence of adult HIV in 2018: Siaya (15.3%). Busia 9.9%, Homa Bay 19.6%, Kisumu 17.5%, and Migori 13.0%. The study county is Busia, where the prevalence is greater than the national average. Vihiga constitutes 5.3% of the county prevalence, as reported by some sources. Kitui 5.7 percent 3.9% Kakamega. Kisii, 6.6 percent 4% Tans Nzoia The Muranga 3% Nyamira 3 percent Makueni 3.9 percent Mombasa, 5.6 percent Kiambu 1.1% and

Taita Taveta 5.2% (KENPHIA, 2018). Other counties with a lower prevalence of adult HIV, as reported in the 2018 Kenya Aids Response Progress Report, were Wajir (0.1 percent), Mandera (0.2 percent), Garissa (0.8 percent), Baringo (1.3 percent), and Marsabit (1.4 percent) (KARPR, 2018). At present, there is a lack of data in Busia County regarding research conducted on food-based nutrition intervention studies for the management of NCDS among individuals living with HIV.

1.2 Statement of the Problem

WHO reports that over 85 percent of NCD-related fatalities transpire in low or middle-income nations (2014). There is a growing prevalence of non-communicable diseases in Sub-Saharan Africa. A number of African studies have documented a substantial prevalence of hypertension, obesity, and hypercholesterolemia among antiretroviral therapy-treated individuals with human immunodeficiency virus (HIV) (Divala et al., 2016). Epidemiological studies indicate a rising trend in the incidence and prevalence of four main risk factors for cardiovascular disease: hypertension, hyperglycemia, dyslipidemia, and obesity, according to Bloomfield et al. (2015). Cancer, cardiovascular and pulmonary disease, and mental health disorders are non-communicable diseases that are most commonly observed in low-income or middle-income nations (Mayosi, 2007). Non-communicable diseases (NCDs), including hypertension and diabetes, are an increasing worldwide public health issue, causing approximately 30 percent of household income loss in Kenya and 39 percent of fatalities, according to the national strategic plan of the Ministry of Health (AMPATH, 2023). Worldwide, there is a persistent increase in the prevalence of noncommunicable diseases (NCDs) (Hunter et al., 2013). Kenya, similar to numerous other nations in sub-Saharan Africa,

grapples with the dual challenge of communicable and non-communicable diseases (NCDs) (Gouda et al., 1990-2017). Presently, 51% of the adult population in Kenya is afflicted with multiple non-communicable diseases (NCDs). Among those without HIV, the burden is comparatively lighter (62%) than among those living with HIV (PLHIV), primarily due to their advanced age profile and the HIV-associated risk for NCDs (Mikaela S et al., 2019). Neurological disorders (NCDs) constituted nearly one-third of all fatalities and fifty percent of hospital admissions in 2015. Diabetes or impaired fasting hypoglycemia affected five percent of the population, while hypertension affected a quarter (MOH, 2015). Diabetes affects over 3.7% of the population in Busia County; however, treatment adherence is limited to 20% (AMPATH, 2023). Additionally, a screening initiative carried out by the Primary-Health Integrated Care for Four Chronic Diseases (PIC4C) project, in collaboration with Community Health Volunteers (CHVs), determined that hypertension impacts more than 25 percent of the adult population in Busia County (AMPATH, 2023).

Several prior investigations have concentrated on the risk factors associated with non-communicable diseases (Kagaruki et al., 2014; Edwards et al., 2015). The present study is distinctive in that it not only identified noncommunicable diseases (NCDs) among people living with HIV (PLHIV) at Busia County referral hospital CCC, but also proved that the application of PROLCARMIV, a plant-based food product containing nutrients recognized for their ability to mitigate NCDs, affected the variables of the study. This suggests that the product may be applicable elsewhere in the context of managing NCDs among PLHIV.

Prior research has demonstrated methodological deficiencies by relying on longitudinal or cross-sectional approaches, whereas it is now common knowledge that randomized controlled trials (RCTs) constitute a crucial body of evidence in the field of health. In order to enhance the efficacy of nutritional interventions, it is imperative to improve the quality of evidence supporting nutritional recommendations (Magni P, 2017). This study presents an alternative perspective by employing the randomized controlled trial (RCT) design.

At the CCC, laboratory testing lagged behind the utilization of other program services; the implementation of PROLCARMIV for PLHIV with NCDs facilitated the expansion of service utilization. Medication-associated elevations in cholesterol and triglyceride levels are prevalent among PLHIV. Altering one's lifestyle to adopt healthier behaviors, such as reducing elevated cholesterol (CHOL) or triglycerides (TG), can effectively mitigate the risk of developing cardiovascular diseases.

As a result, the purpose of this study was to investigate the impact of a food-based nutrition intervention on the management of noncommunicable diseases (NCDs) among PLHIV in order to develop an integrated strategy for HIV and NCD care and management.

1.3 Objectives of the study.

1.3.1 Broad objective of the study

To determine the effect of the Food based Nutrition intervention on management of NCDs among PLHIV at the CCC in Busia County referral hospital**.**

1.3.2 Specific objectives

1. To establish the prevalence of NCDs among PLHIV at the CCC in Busia County referral hospital, Kenya.
2. To determine anthropometric measurements of PLHIV with NCDs at the CCC in Busia County referral hospital, Kenya.
3. To assess dietary practices for PLHIV with NCDs at the CCC in Busia County referral hospital, Kenya.
4. To establish baseline lipid profile, random blood sugar levels, hemoglobin levels, liver and kidney function of PLHIV with NCDs at the CCC in Busia County referral hospital, Kenya.
5. To determine the effect of use of standard food product and treatment food product among PLHIV with NCDs at the CCC in Busia County referral hospital in western region of Kenya.

1.4 Research Questions

1. What is the prevalence of NCDs among PLHIV at the CCC in Busia County referral hospital in Western Region of Kenya?
2. What is the nutritional status of PLHIV with NCDs at the CCC in Busia County referral hospital Western Region Kenya?
3. What are the dietary practices of people living with HIV at the CCC in Busia County referral hospital in Western Region of Kenya?

4. What is the baseline lipid profile, Random blood sugar levels, hemoglobin levels, liver and kidney function of PLHIV at the CCC in Busia County referral hospital, Western Region of Kenya?
5. What is the effect of standard food product and treatment food product on PLHIV with NCDs at the CCC in Busia County referral hospital in Western Region of Kenya?

Alternative Hypothesis

There is a significant difference between the use of standard food product and treatment food product among PLHIV with NCDs at the CCC in Busia County referral, Kenya.

1.5 Justification of the study

Many studies have been conducted on NCDs and HIV in Kenya, but have insufficient data on successful use of a food based nutrition intervention on management of NCDs among PLHIV. The current study has plumby nut (RUFT) fed to the control group while power porridge (PROLCARMIV) for the intervention group. The effect of the PROLCARMIV on the management of NCDS among PLHIV may advice the current National policy on management of HIV and NCDs which largely encourages use of conventional medicine rather than having nutrition as an integral element in the management of the two.

Both the nutrition products in this study are plant based, plumby nut has highly processed ingredients, but not locally available and the costs are high not affordable by the study population, while the power porridge has locally available ingredients grown produced and consumed by the study subjects in Busia and Kenya as a whole. The Academic Model Providing Access to

Healthcare (AMPATH, 2023), Kenya Medical Research Institute (KEMRI, 2022) and others have conducted studies in Busia but largely on prevalence of NCDS and cost effectiveness of implementing care services. Information from this study may be vital to inform the national and county policies on the management of NCDs among PLHIV. This will also add knowledge to existing literature on management of NCDs among PLHIV in the Kenyan context. Additionally, the nation is undertaking the implementation of the Big Four Agenda, with universal health care being a primary objective. This study holds significance for this agenda as it examines two of the most prevalent causes of mortality not only in Kenya but also globally. Optimal disease control is one of the global initiative's Vision 2020 priority areas. In an effort to alleviate the burden of noncommunicable diseases (NCDs), the researcher contributed to this effort by gathering data on the management of NCDs among PLHIV in this study. Non-communicable diseases (NCDs) also pose a challenge to the advancement of the 2030 Sustainable Development Agenda, which stipulates a reduction of premature fatalities caused by NCDs by one-third by 2030.

1.6 Significance

Though there is a lot of evidence that non - communicable diseases among people with HIV are on the increase, the results of this study may reduce the knowledge gap that exists in managing NCDs among PLHIV with food based interventions. HIV/AIDS and nutrition are intricately intertwined. Malnutrition may both be a factor in the progression of HIV and a consequence of it. This relationship between malnutrition and HIV/AIDS creates a vicious cycle: HIV compromises the immune system, which in turn increases the risk of infection. To improve the nutrition status and quality of life of the study

participants, the researcher formulated power porridge using locally available ingredients as a strategy to manage noncommunicable diseases (NCDs). The study is in tandem with the increasing commitment by the Kenyan Government to address nutrition related diseases and conditions evidenced by formulation of a Food and Nutrition Security Policy (FNSP), a National Food Security and Nutrition strategy that aim to address nutrition security in the country, and recently introduction of Nutrition Sensitive Agriculture Policies and activities. These policies place nutrition central to human development; emphasize the need to ensure right to nutrition, recognize disparities in nutrition; provide relevant policy directions and a multi-sectorial approach to addressing nutrition in the country. Kenya is committed to reduce morbidity and premature mortality that result from NCDs and promote the well-being of Kenyans through Kenya National strategy for prevention and control of non-communicable disease and KHSSP III 2013-2017, that nutrition is integral in it. This study aims at supporting all these initiatives to ensure that Kenya as a country is able to achieve its goals of Universal health for all, health and well-being for all and food and nutrition security.

1.7 Scope of the Study

This study was conducted in the Comprehensive Care Clinic (CCC) at the Busia County referral hospital. The study subjects were PLHIV with NCDs, aged 18 years and above were identified, selected and assigned equally into control and experimental groups for a food based nutrition intervention. The control group was feed on Plumbynut while the experimental groups were

feed on power porridge (duped PRLOCARMIV) for 60 days. Baseline data was collected by administration of a structured questionnaire, phlebotomy and urine collection were done for baseline and post - intervention laboratory analyses.

1.7. 1 Limitations

The Covid pandemic caused a delay in commencement of the research at the Busia County referral Hospital.

The study subjects are a vulnerable population; therefore attrition rates due to sickness led to dropouts hence reduced the research sample size.

1.7.2 Delimitations

The study was limited to PLHIV with NCDs enrolled in CCC in Busia County referral hospital.

1.7. 3 Assumptions of the Study

The following were study assumptions:

1. That permission to carry out the study would granted and in good time.
2. That funds are available on time and throughout the study

1.8 Theoretical Model

1.8.1 Health Belief Model

Social psychologists at the U.S. Public Health Service created the Health Belief Model (HBM) in the early 1950s to explain why individuals do not utilize screening tests or disease prevention strategies for early detection (Rosenstock et al., 2000). The

HBM was utilized to depict the subjects' behavior in this research as they embraced the food-based nutrition intervention and utilized additional services offered by the CCC. The objective was to enhance the subjects' quality of life (QOL) while simultaneously managing HIV and non-communicable diseases (NCDs). The researcher selected the HBM due to its suitability for assessing patients' adherence to medical treatments and symptom responses. Hypothesis-Based Modeling (HBM) posits that an individual's propensity to adopt a recommended health behavior or action can be predicted by combining that person's belief in the efficacy of the behavior and the personal threat of illness or disease. In the context of this study, the behavior in question pertains to the modification of lifestyle choices as a means to enhance quality of life. The HBM has been extensively utilized to comprehend HIV and antiretroviral therapy (ART) behaviors, with improved adherence among individuals living with HIV in Tanzania, Italy, and the USA correlated with perceptions of enhanced self-efficacy, susceptibility, and treatment benefits (Rosenstock et al., 1994; De Paoli et al., 2004; Fumaz et al., 2008). However, the theory has limited application in individuals who have HIV and non-communicable diseases (Juma et al., 2018).

The HBM is grounded in psychological and behavioral theory and is predicated on the notion that health-related behavior consists of two elements: the intention to prevent illness or, alternatively, to recover from it; and the conviction that a particular health action will either avert or remedy illness. The ultimate decision of an individual frequently hinges on how that person perceives the advantages and disadvantages associated with engaging in health-promoting behaviors. The HBM comprises six distinct constructs. The initial four constructs were formulated as the foundational principles of the HBM. The final two were incorporated into the HBM as research progressed.

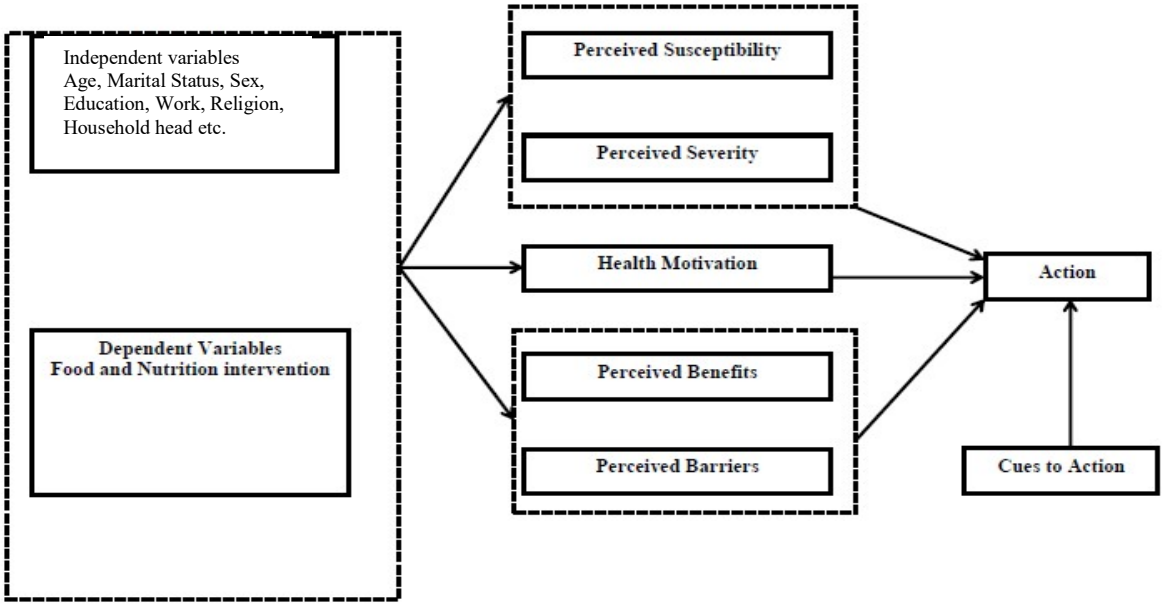


Figure 1: The original HBM (modified to illustrate the behavior of the study population, it was adopted due to its appropriateness).

Perceived susceptibility pertains to the uninformed subjective assessment of the risk associated with a previously acquired ailment or disease by PLHIV with NCDs. Diverse individuals experience varying degrees of personal vulnerability in relation to their illness or disease.

The subject's perception of the severity of the contracted illness or disease (or the consequences of leaving the illness or disease untreated) is referred to as perceived severity. Individuals frequently consider both the medical and social repercussions (e.g., disability, mortality) and family life, as well as social relationships, when assessing the severity. This variation in severity perception is not uncommon.

The concept of perceived benefits pertains to how individuals perceive the efficacy of different measures that are accessible for mitigating the risk of illness or disease (or for curing said illness or disease). Individuals make decisions regarding the prevention or treatment of illnesses or diseases based on their assessment and evaluation of perceived susceptibility and perceived benefit. In this instance, the individual would be more likely to adopt the recommended health action, which is a food-based intervention, if they perceived it to be beneficial.

Perceived barriers are the subject's subjective evaluations of the difficulties associated with implementing a suggested health behavior. An individual's perception of obstacles or hindrances varies considerably, necessitating a cost-benefit analysis. The individual assesses the efficacy of the actions in light of the perceptions that they may be costly, hazardous (e.g., adverse effects), distressing (e.g., painful), time-intensive, or inconvenient.

A stimulus that initiates the decision-making process to adopt a recommended health action is referred to as a "cue to action." These cues may manifest internally (e.g., wheezing, chest pains) or externally (e.g., advice from others, a family member's ailment, a newspaper article).

Self-efficacy pertains to the degree of assurance that an individual has in their own capability to execute a particular behavior with success. The most recent addition to the model of this type occurred in the mid-1980s. Numerous behavioral theories include self-efficacy as a construct, since it is directly related to whether or not an individual executes the desired behavior.

1.8.2 Strengths and weakness of the HBM:

Strengths

One notable advantage of the HBM is its utilization of simplified health-related constructs, which facilitate its implementation, application, and evaluation (Conner, 2010). Since more than three decades ago, the HBM has furnished a practical conceptual framework for examining the cognitive determinants of a vast array of behaviors. Once more, it has directed the interest of researchers and health care professionals toward variables that serve as preconditions for health behavior. As a result, it has served as a foundation for numerous pragmatic interventions encompassing various behaviors (Jones et al., 1987). Nonetheless, it is not devoid of restrictions.

Weaknesses

One primary critique of HBM pertains to the absence of explicit delineation of the interrelationships among variables and the lack of definitive guidelines regarding the combination of formulated variables (Armitage and Conner, 2000; Sheeran and

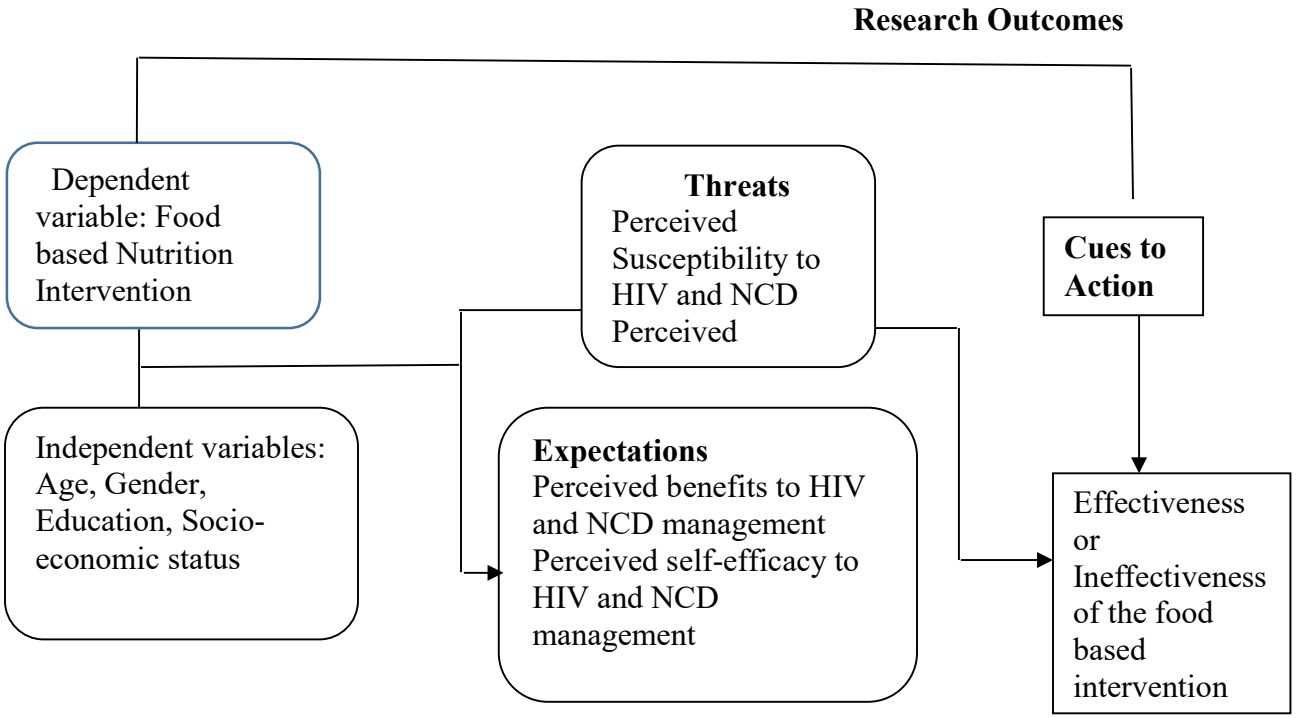
Abraham, 1996). However, this weakness can also be viewed as a strength, as the HBM is adaptable and applicable to numerous health behavior and population groups due to the flexibility provided by the absence of precise rules of combination. The second significant drawback of HBM pertains to its predictive capacity. In the majority of instances, the primary variables (susceptibility, severity, benefits, and barriers) were significant predictors of health-related behavior, according to the findings of quantitative analyses of the HBM. Although this is the case, their effect sizes are typically quite modest (Harrison et al., 1992; Abraham and Sheeran, 2005). This indicates that there may be additional significant determinants of healthful behavior that HBM has failed to consider. Therefore, notwithstanding its extensive adoption by researchers in the field of healthy behavior promotion, the model remains inadequate.

1.9 The Conceptual Framework

The conceptual framework utilized in this investigation was adapted and modified from Matthew et al.'s Health Policy and Planning (2019). The concept provides further details regarding the impact of the food-based nutrition intervention on the study participants' actions and behaviors in response to the positive research outcomes. Each participant in the study was influenced in their informed decisions and choices by sociodemographic variables. The disparities in HIV prevalence across various geographic regions can be attributed to the following variables: employment, illiteracy, and being below 30 years old account for high rates of HIV infection in a given area. These variables are observed to have an impact on the study populations. As non-communicable diseases, NCDs necessitate that research participants make informed dietary decisions. Similarly to the transmission of HIV, sociodemographic factors, which are significant in this particular study, exert a

substantial influence on the study's results. NCDs are intricately linked to poverty. It is anticipated that the exponential growth of non-communicable diseases will hinder efforts to reduce poverty, specifically by escalating healthcare expenses for households. Additionally, gender impacts the prevalence of HIV and NCDs. In this study, women were more susceptible to both NCDs and HIV than men.

Figure 2: Proposed version of the HBM that illustrates HBM concepts and how they affect the study outcomes



Source: Adopted and Modified from Matthew et al., (2019), Health Policy and Planning

CHAPTER TWO

LITRATURE REVIEW

2.1 Overview of HIV and NCDs

The increased risk of noncommunicable diseases (NCDs) among PLHIV may jeopardize the efficacy of ART by resulting in untimely morbidity and mortality. Hence, in this group of patients, it is critical to identify and control risk factors associated with non-communicable diseases (Leung, 2016). HIV and NCD are both complex conditions that necessitate a diverse array of factors to be taken into account, such as dietary and nutrition therapy, regular laboratory and clinical monitoring, modifications in behavior, and assistance with adherence (Rabkin, 2012). In order to address health concerns, one must have knowledge of adequate nutrition, dietary diversity, dietary practices, and traditional food patterns. Malnutrition manifests itself in diverse ways, encompassing deficiencies in essential nutrients, inadequate nutrition, excessive weight, obesity, and non-communicable diseases (Weerasekara et al., 2020). Our nutritional status and the foods we consume can influence cardiovascular disease, certain types of malignancy, and diabetes. Diet, nutritional status, and specific foods are additionally correlated with insulin resistance, hypertension, and elevated blood cholesterol and blood pressure. In addition to being significant causes of illness, these conditions are risk factors for noncommunicable diseases (Sanjay et al. 2014). Adhering to a plant-based diet predominately decreases the likelihood of developing certain types of cancer, obesity, diabetes, and cardiovascular disease. Vegetables and fruits, whole grains, pulses, nuts, and seeds predominate in plant-based diets, which contain only trace quantities of meat and dairy. In addition to promoting weight loss and maintenance, lowering blood pressure, and providing an

abundance of dietary fiber, which protects against colorectal cancer, these regimens also aid in these objectives (World Cancer Research Fund International, 2014). This research investigated the impact of a food-based nutrition intervention that primarily comprised plant-based foods, with an emphasis on soybeans, millet, pumpkin, and pistachio nuts.

2.2 Syndemic relation between HIV and NCDs and infections

The association between HIV and CVD may be attributed to conventional CVD risk factors, HIV-mediated inflammation, and ART adverse effects. Mortality and morbidity associated with CVD endpoints are significantly higher among individuals living with HIV in developed nations, according to a multitude of studies (Kamin; Grinspoon, 2005). Weight being the only traditional CVD risk factor for which the prevalence was comparatively similar between HIV-positive and non-HIV individuals, this study revealed. Research conducted in the United States and Europe has reported a higher prevalence of myocardial infarction in HIV-positive individuals, when accounting for conventional risk factors, in comparison to non-HIV individuals (Lang; Mary–Krause, 2010). Obstacle-follow-up care may account for the decline in prevalence of hypertension among the elderly living with HIV in Uganda, according to prevalence studies (Mugisha, 2016). Thus, PLHIV on ART are more susceptible to developing metabolic syndrome and adipose redistribution, both of which may increase the risk of cardiometabolic disease in this population (Wand, 2010). According to a study of South African public school educators (Zungu et al., 2019), 36.9% of educators who were HIV-positive also suffered from non-communicable diseases, with 17.4% having hypertension. It is worth mentioning that there was a considerably higher likelihood of non-communicable disease

(NCD) reporting among females compared to males (Aor=1.5: 95% CI). In a similar vein, Achwoka et al. (2019) examined the medical records of PLHIV adults in Kenya retrospectively and found that 11.5% had a documented non-communicable disease (NCD), with hypertension being the most prevalent at 87.5% (n=343).In their research conducted in Lubowa, Uganda, Kansiime et al. discovered that the prevalence of having at least one non-communicable disease (NCD) was 20.7% (95% CI: 16.7-24.5). Data extracted from routine care patient files were utilized in the study to identify patients with NCDs.

2.3 Prevalence of NCDs among PLHIV

Recent years have witnessed the elucidation of mechanisms by which HIV elevates the risk for a number of NCDs. Inflammation of the blood vessels can be induced by HIV, which increases the risk of cardiovascular disease by promoting the development of atherosclerosis and high-risk plaque (Eugenin et al., 2008). Furthermore, it has been demonstrated that certain anti-retroviral medications employed in the treatment of HIV can elevate abdominal obesity, cholesterol, and blood pressure (Krishnan et al., 2015). Additionally, metabolic syndrome and insulin resistance have been associated with ART (Brown et al., 2005). Scholars conducted investigations in Botswana, Malawi, Nigeria, Tanzania, and Zimbabwe, where individuals living with HIV who were prescribed antiretroviral therapy (ART) encountered elevated prevalence rates of hypertension and diabetes mellitus in comparison to the general populace (Kagaruki et al., 2014; Magodoro, Esterhuizen, & Chivese 2016). An additional investigation revealed a significantly high prevalence of diabetes mellitus, hypertension, and hyperlipidemia among individuals of both genders who were living with HIV in Cambodia. As stated by Chhoun et al. (2017). The respective

prevalence rates for hypertension, diabetes mellitus, and hyperlipidemia were 33.7%, 15.1%, and 9.4%. In comparison to women, the incidence of hyperlipidemia was considerably greater in the male population. Additionally, in males, mean systolic and diastolic blood pressures were considerably elevated. Consequently, their findings demonstrate the criticality of implementing individualized interventions to screen, refer, prevent, and treat non-communicable diseases (NCDs) among individuals living with HIV. In Cambodia, there was a significant prevalence of diabetes mellitus, hypertension, and hyperlipidemia among men and women who were living with HIV. The research team administered a structured questionnaire to gather information pertaining to socio-demographic attributes, health-related behaviors, medical background, and antiretroviral therapy (ART). Furthermore, biological and anthropometric measurements were conducted and will be discussed in the following section.

Additionally, individuals infected with HIV have a higher prevalence of hypertension, diabetes, and dyslipidemia (Alvarez et al., 2010). Research has indicated that the prevalence of hypertension among adults living with HIV in Malawi can range from 24% to 46% (Divala et al., 2016).

According to a study by Mathebula et al. (2020), the prevalence of hypertension among HIV patients on HAART was 34.6%, which is lower than the 38% prevalence observed in Cameroon (Shah et al., 2012). Men had a greater prevalence of hypertension than women in this study, which is consistent with the results reported by Chhoun et al. (2017). The current study found that the prevalence of hypertension was 41.3% among men and 32.1% among women. These figures are consistent with those of a study conducted in Kenya, which found that the prevalence of hypertension was 11.2% among men and 7.4% among

women (Deeks and Philips 2009). Additionally, the results once more indicated that males aged 55 years and above had the highest prevalence of hypertension (60 percent), which contradicts the findings of Bloomfield et al. (2011), who discovered that the prevalence was greater among younger men compared to older age groups. One possible justification is that elderly men might not have the capacity to regulate their blood pressure and stress levels to the same extent as younger men. In conclusion, males appear to be more prevalent than women among those with NCDs. The prevalence of hypertension was 12.4%, diabetes mellitus was 4.7%, and cardiomyopathy was 1.3%, according to Kansiime et al. (2019). Conversely, the prevalence was considerably greater among the elderly participants in their research, excluding those who also exhibited an opportunistic infection. The purpose of the present investigation is to determine the prevalence of NCDs among PLHIV so that comparisons and conclusions can be drawn.

2.4 Anthropometric measurements and dietary practices among PLHIV with NCDs

According to Mathebula et al.'s (2020) study on the prevalence of specific risk factors for non-communicable diseases among people living with HIV who are receiving anti-retroviral medication, the prevalence of overweight was 21.4% overall, with a slightly higher prevalence among women than among men (21.7 and 20.7%, respectively). The prevalence of obesity was 19.6% overall, with females having a higher prevalence of 22.5% compared to males. In comparison to males, the prevalence of aberrant waist circumference was 4.4%, while it was 42.5% among females, representing an overall prevalence of 31.9%. The prevalence of smoking was found to be 10.8% overall, with males having a higher prevalence of 32.6% compared to

females' 2.5%. In their study, Chhoun et al. (2017) examined dietary habits and found that participants consumed fruits an average of 1.8 servings (SD = 5.2) per day, or 2.5 days per week (SD = 2.1). They indicated that they consumed vegetables an average of 2.0 servings (SD = 0.5) per day, on 5.6 days per week (SD = 1.7). A significant proportion of the participants (92.4%) indicated that they routinely prepare their meals at home. Vegetable oil was the prevailing culinary oil utilized by 95.3% of respondents. Lard was reported by 4.3%, and animal fat was utilized by 0.4%, when it came to meal preparation. The percentage of women who reported doing the majority of their meal preparation at home was considerably higher (97.9% vs. 81.2%, $p < 0.001$). Patients in a separate study (Kagaruki et al., 2014) reported inadequate consumption of fruits and vegetables (70 percent) and insufficient engagement in vigorous physical activity (48 percent). Using comparable instruments, the present study will also examine patients' engagement in vigorous physical activity in addition to their dietary habits.

2.5 Effect of HIV and NCDs on study variables

Dillon et al. (2012) note that HIV infection is linked to higher triglycerides and lower HDL, as well as lower body mass index and higher blood pressure, but that antiretroviral therapy (ART), and particularly protease inhibitors, appear to raise LDL and HDL while reducing glycated hemoglobin (HbA1C). Consequently, they are more prone to developing non-modifiable risk factors, including age, as well as modifiable risk factors like obesity (Sabin and Worm 2008). In their research on the prevalence and risk factors of non-communicable diseases among individuals living with HIV in Tanzania, Kagaruki et al. (2014) observed a comparable pattern in two Tanzanian regions (rural and urban). Among the 671 PLHIV patients analyzed,

26.0% had hypertension and 4.2 percent had diabetes mellitus. NCD risk factors that were prevalent included aberrant waist circumference (47%), low HDL (72%), and high LDL (43%). Subjects in this research endeavor were provided health education and treatment in accordance with the results obtained from laboratory analysis and the collection of baseline data.

2.6 Strategies in Kenya for nutrition support among PLHIV

Malnutrition prevention programs for people living with HIV/AIDS in Kenya often fall into one of three categories: short-term, medium-term, or long-term. The short-term strategy is predicated on nutritional and food supplementation; these typically consist of ready-to-eat therapeutic foods or flours that are ground into porridge for the patient. The clients undergo assessment at the CCCs, and those identified as vulnerable in accordance with national guidelines are counseled and offered an appropriate nutritional supplement or food supplement as a preventative or therapeutic measure against malnutrition. Multiple donors, including the Nutrition and Health Programme (NHP-plus), USAID, the Global Fund, and the United Nations World Food Programme, support this initiative. The Nutrition and HIV Programme was established in 2005 by the Ministry of Health (MOH) in collaboration with NASCOP to combat malnutrition among PLHIV. The subsequent interventions have been identified and elaborated upon.

Supplementation as an intervention involves the administration of essential nutrients directly into the bodies of clients via oral (pills, capsules) or intramuscular means. Supplementation is frequently employed as a temporary but efficacious measure in the interim, while more permanent intervention strategies are being devised. In Kenyan healthcare facilities, this approach is

extensively employed to administer vitamin A and iron supplements, primarily to children and adults, in accordance with the guidelines set forth by the national policy. The second step is food fortification, which entails the incorporation of micronutrients into food vehicles, including oils, fats, sodium, and sugar, which are frequently consumed by vulnerable populations. As of now, culinary oils in Kenya have been supplemented with Vitamin A. Potassium iodate is used to fortify salt, whereas micronutrients such as vitamin A and iron are added to maize flour.

Dietary Diversification is an intervention that educates individuals on how to improve their diets through the use of nutrition communication techniques and informal channels. Additionally, it assists them in identifying practical measures that can be implemented to enhance the production and consumption of affordable foods that are abundant in macronutrients and micronutrients. This proposed research prioritizes this specific methodology on account of its increased community participation and simplicity of sustainability. Ministries and organizations including the Ministries of Education, Agriculture, Health, Culture, and Social Services, and Education via School Health Programmes, are examples of such entities. Non-governmental organizations and community-based organizations. Nutrition education is a component of each and every intervention strategy. Urgent advocacy is required to address the malnutrition problem among PLHIV through the implementation of more long-term interventions; initiatives focusing on food-based strategies, such as food diversification, must be increased. It is essential to emphasize a well-organized promotional campaign for both production and consumption. Although the promotion may yield short-term results, it is imperative that the change agents are adequately trained and inspired to disseminate the message to additional community members.

2.7 Research Contributions to policy and practice

This research has presented a chance to promote the utilization of locally sourced foods that were incorporated into the formulation of PROLCARMIV. The communities will experience an increase in income when the local producers and businessmen and women adopt the proposed strategy.

As a result of the increased utilization of other services at the CCC resulting from the implementation of a food-based nutrition intervention, a one-stop shop for HIV and NCDs was suggested for the CCC.

Additionally, an endeavor was made to provide a practical solution to food, nutrition, and dietetics issues at the CCC.

The integration of community services for PLHIV and NCDS with clinical services can be achieved via the food-based nutrition intervention.

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2.8 Gaps in Knowledge

The current global burden of HIV and NCDs is enormous, according to a review of the relevant literature; however, there is limited evidence regarding Food, Nutrition, and Dietetics interventions for the prevention and management of NCDs among PLHIV.

Although the Kenya Nutrition and HIV Guidelines are policy guidelines at the national level, there is a current deficiency in the management of NCDS nutrition among PLHIV.

The subsequent information is standardized nutrition and dietary guidance derived from policy guidelines and provided to asymptomatic adults and children infected with HIV. They necessitate approximately 10% more energy than their non-infected peers.

Adults with symptomatic PLHIV have increased energy requirements by 20–30%, while minors undergoing weight loss experience an increase of 50–100%.

Pregnant and lactating women who are infected with HIV necessitate an additional 23–50% of their body weight in energy, contingent upon factors such as symptom severity, maternal health, and lactation status. Sufficient consumption of staple foods can fulfill these requirements. It is feasible to fulfill the energy needs of PLHIV by incorporating nutrient-dense snacks into their diet, increasing their consumption of energy-rich foods, and employing innovative food processing techniques (e.g., sprouting, blending, and fermenting).

Adequate protein consumption, ranging from 50-80 g per day or 12-15 percent of total energy needs, is sufficient for supporting tissue growth, maintenance, and repair, as well as immune function, in individuals without or with HIV. Children, as well as women who are expectant or lactating, must consume animal proteins. A daily variety of foods derived from plants in Kenya is necessary to guarantee sufficient and high-quality protein. Consuming foods derived from animals, including dairy products, poultry, meats, and fish, increases the likelihood of obtaining sufficient protein. XI. Kenyan National Nutrition and

HIV/AIDS Guidelines Micronutrients, including vitamins and minerals, are necessary for the synthesis and operation of proteins, enzymes, hormones, and the immune system. The most essential nutrients include vitamins A, C, E, folate, B group vitamins, iron, zinc, selenium, iodine, magnesium, and calcium. It is imperative to maintain PLHIV requirements at a single Recommended Daily Allowance (RDA). A daily intake of a diverse selection of protective foods, including fruits, vegetables, and animal products, will furnish sufficient micronutrients and a substantial portion of the recommended daily fiber intake (15-25 g). Supplementation with multiple micronutrients, dietary diversification, and food fortification all contribute to the fulfillment of Recommended Daily Allowances (RDA). Furthermore, it is recommended that HIV-positive infants and lactating women take iodine and vitamin A supplements, as suggested by the World Health Organization (WHO) and Ministry of Health (MOH). During pregnancy, iron-folate and iodine supplements should also be administered.(MOH, 2014)

In Kenya, nutritionists and dietitians who are in practice lack inexpensive, locally accessible products known to aid in the management of NCDS, such as PROLCARMIV. In light of this context, the purpose of this research was to generate empirical support for the impact of food-based nutrition interventions on the prevention of noncommunicable diseases (NCDs) among HIV-positive individuals. Experts and researchers in health and nutrition policy must conduct additional studies on food-based nutrition interventions aimed at mitigating the excessive dependence on conventional medicine for the treatment and management of non-communicable diseases (NCDs) among PLHIV.

CHAPTER THREE

RESEARCH METHODS AND MATERIALS

3.1 Introduction

This chapter explains how the researcher planned and carried out the study. It includes the study area, study design, sampling procedure, study population, data collection method, tools and statistical analysis. The research methodology is ultimately a methodological and systematic plan that the researcher used to try and resolve the research problem. Further to this, the researcher explained how the research idea was turned into a study, which in turn produced valid and reliable results that are in accordance with the aims and objectives of the research.

3.2 Study Area

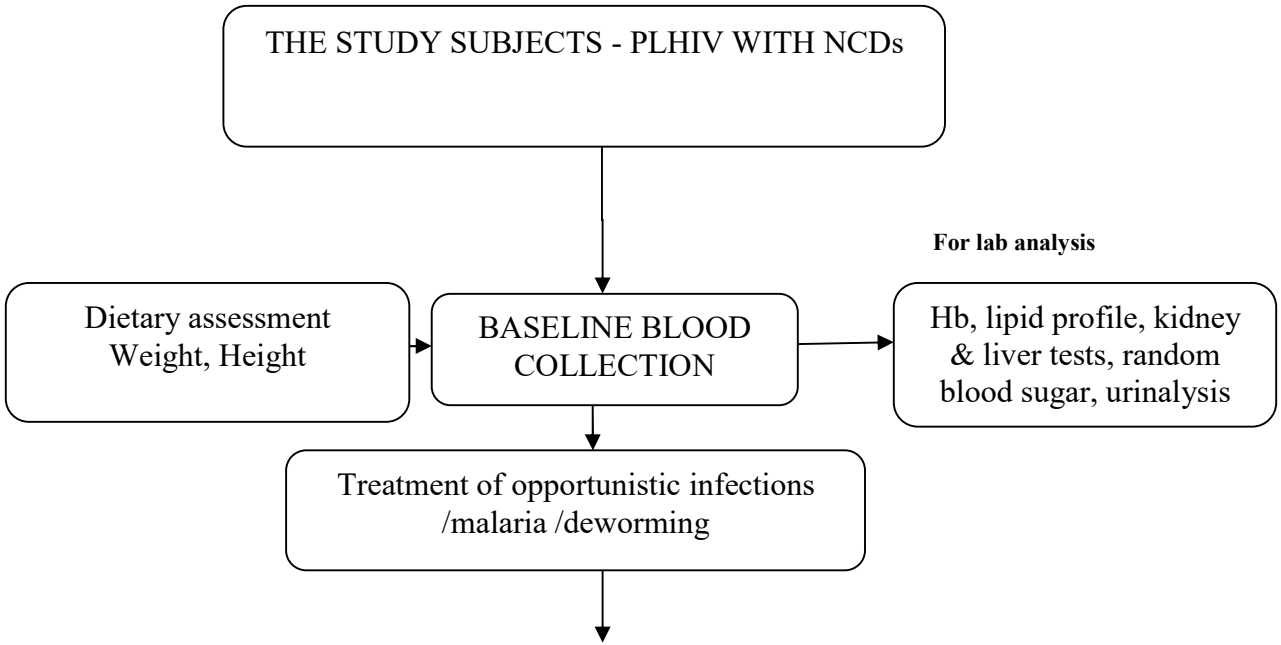
The study took place in Busia, County in the Western Region of Kenya. The County borders westwards with the Republic of Uganda; this makes the border a business hub hence high chances of having men and women at risk of HIV, studies have shown that the prevalence of HIV in Busia is higher than the National rates. The inhabitants of Busia County practice fishing for a living and hence fish for sex has been document in this county especially around Lake Victoria. The County has an approximate area of 1261 square kilometers; this includes 137 kilometers squares, (which is also under permanent water

surface). The main economic activity is agriculture with emphasis on food crops namely; sweet potatoes, maize, cassava, groundnuts, indigenous vegetables, millet, maize, simsim, bananas and beans, and cash crops such as sugar cane.

3.3 Study Design

This was an experimental study using the randomized control trial approach. The study had two arms of study groups whereby one group was the control group and the other one was treatment group. The control group had PLHIV with NCDs fed on ready to eat therapeutic food while the treatment group had PLHIV with NCDs and they were fed on a power Porridge (PROLCARMIV). Control for duration of ARV was used by selecting patients who were on first line treatment. After controlling for other confounding factors such as opportunistic infections, Malaria and Worms the feeding was initiated for both arms of the study.

The diagram below is a detailed summary of the research design.



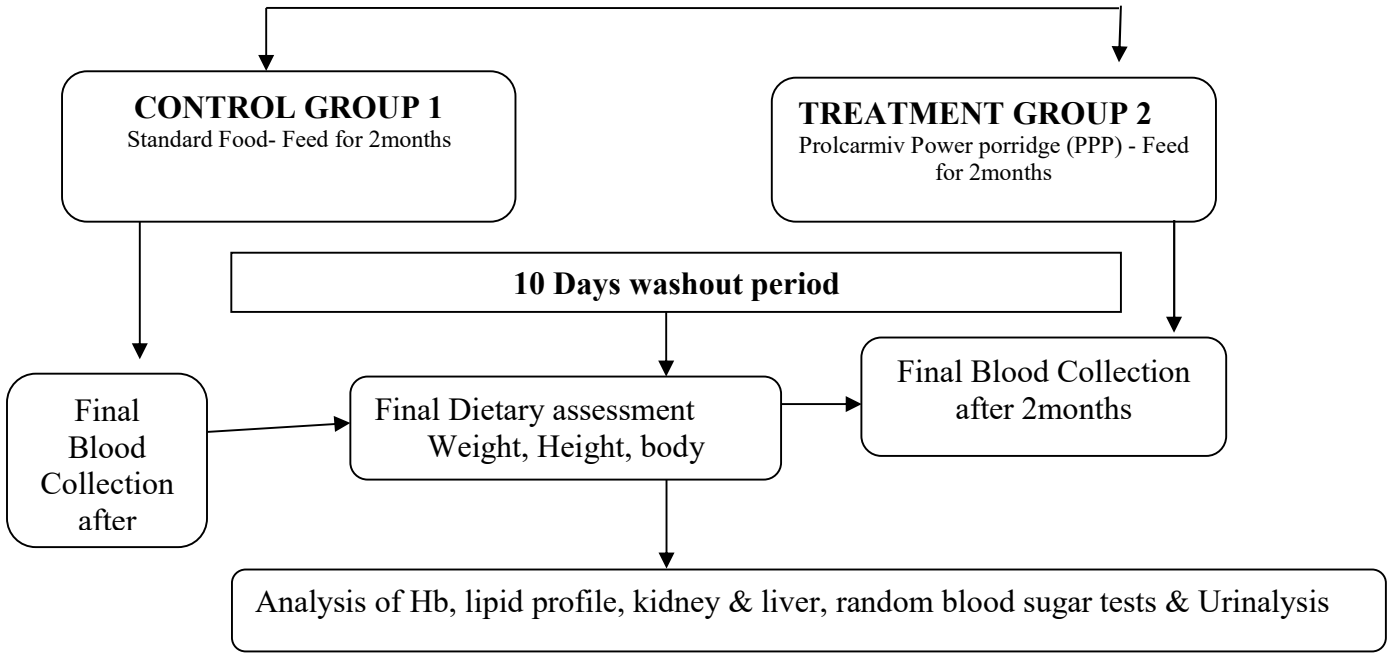


Figure 3: A Schematic diagram of research design

3.4 Study Population

Study subjects were People Living with HIV (PLHIV) with NCDs, aged 18 years and above, they were purposefully selected from Busia County referral hospital CCC and randomly placed in two groups to participate in the study.

This study population was selected because not many food, nutrition and dietetics interventions have been developed to help alleviate the problem of NCDs among PLHIV. NCDs particularly were chosen by the researcher and not communicable diseases, because the NCDs problem is on the increase among PLHIV and communicable disease has been controlled among the same population.

Busia County exhibits the tenth highest HIV prevalence rate in the nation. Specifically, the HIV prevalence in Busia County is 1.1 times greater than the national average, standing at 6.7%. According to the report of Busia County Partners in 2018, the county accounted for 1.4% and 2.0% of the overall new HIV infections in Kenya among children and adults, respectively.

3.4.1 Inclusion Criteria

All PLHIV with NCDs who presented at the CCC and who consented, aged 18years and above, and were on 1st line treatment (Lamividine (TC)in combination with Nevirapine/Efavirenz and Zodovidine (AZT)

3.4. 2 Exclusion Criteria

The following categories of people were not included in the study;

1. Children under the age of 18 years - Treated at the pediatric clinic not at the CCC
2. PLHIV without NCDS

3. Expectant Women - Prevention of Mother to Child Transmissions (PMCTC are found at the MCH clinic
4. Not consented
5. Clients not registered at the CCC
6. The mentally sick persons with HIV
7. PLHIV with deteriorated quality of Life
8. Full blown HIV and AIDS

3.5 Study Measurable Variables

The variables analyzed at baseline and post- intervention included, Anthropometrics dietary practices, Cholesterol levels, hemoglobin levels, blood sugar levels, Proteins in urine, Specific Gravity (SG), Leucocytes, Low Density Lipoproteins (LDL), high Density Lipoproteins (HDL), Triglyceride, Alanine Transminase(ALT),Aspartate (AST) Transaminase, Alkaline Phosphatase(ALP),Gamma Glutamyl transferase (GGT), Total Protein (PT), Bilirubin Time(BT), and Albumin levels.

3.5.1 Independent variables

Age, Gender, Education, Socio-economic status.

3.5.2 Dependent Variables

Food based Nutrition Intervention.

3.6 Sampling

3.6.1 Sampling Procedure

Sampling refers to the systematic procedure employed to pick a subset of individuals from a larger population, with the aim of ensuring that the chosen individuals are representative of the overall group from which they were drawn (American Journal of Educational Research, 2020). In this research a sub group of PLHIV with NCDs was purposively selected from a larger group of PLHIV coming for services at the Busia County Referral hospital CCC.

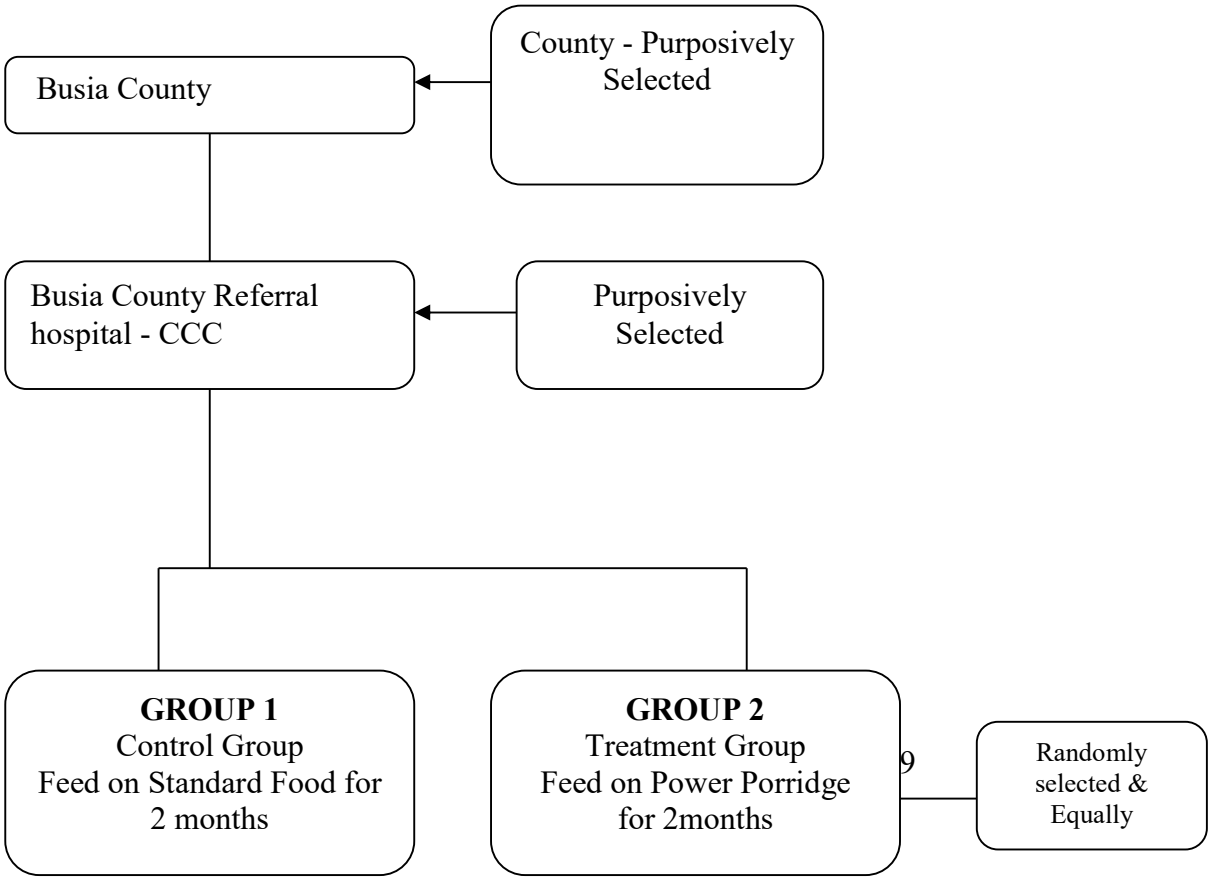


Figure 4: Summary of the Sampling Procedure

3.6. 2 Sampling of Study Site

Busia County referral hospital was purposively selected, because it is a large CCC, well-populated with PLHIV clients due to its proximity to the boarder of Kenya and Uganda, which is a hub of business activities which poses risky practices that, could lead to increase of HIV infections.

3.6.3 Sampling of Study Respondents

A sub group of PLHIV with NCDs were randomly selected, using simple random sampling procedure (lottery) and equally assigned to two intervention arms of the study, the control and the treatment group **(summarized in figure 3.2)**

3.6.4 Sample size determination by - G* Power

G*Power is a software application utilized for the computation of statistical power. The software provides the capability to compute statistical power for a diverse range of tests, such as t-tests, F-tests, and chi-square tests, among other options. Moreover, the user is required to ascertain the specific situation in which this test is being employed, such as distinguishing between a one-way ANOVA and a multi-way ANOVA. To compute power, it is necessary for the user to possess knowledge

of four out of five variables, namely: the number of groups, the number of observations, the effect size, the significance level (α), or the power (1-β). G*Power provides a built-in feature for assessing effect size in cases when it cannot be predicted from existing literature or is not readily calculable.

F tests - MANOVA: Repeated measures, within-between interaction

Options: Pillai V, O'Brien-Shieh Algorithm

Analysis: A priori: Compute required sample size

Input:	Effect size f(V)	=	0.5
	α err prob	=	0.05
	Power (1-β err prob)	=	0.95
	Number of groups	=	2
	Number of measurements	=	2
Output:	Noncentrality parameter λ	=	13.5000000
	Critical F	=	4.0266314
	Numerator df	=	1.0000000
	Denominator df	=	52.0000000
	Total sample size	=	54

Actual power = 0.9500773

Pillai V = 0.2000000

Note: This sample 54 was used with 10% attrition rate.

Target sample 54 Subjects with 10% attrition rates = 59 subjects.

Approximately 60 subjects purposively selected and then randomly selected and assigned equally to the two arms of the study.

3.6.5 Sampling Frame

Study subjects were randomly selected from PLHIV attending the Busia County Referral hospital CCC and equally assigned to their specific study groups as follows;

Control group was assigned 30 subjects (after calculation of attrition rates) while the intervention group was assigned 30 - equal number of subjects leading to a total number of 60 participants

Figure 5: Consort

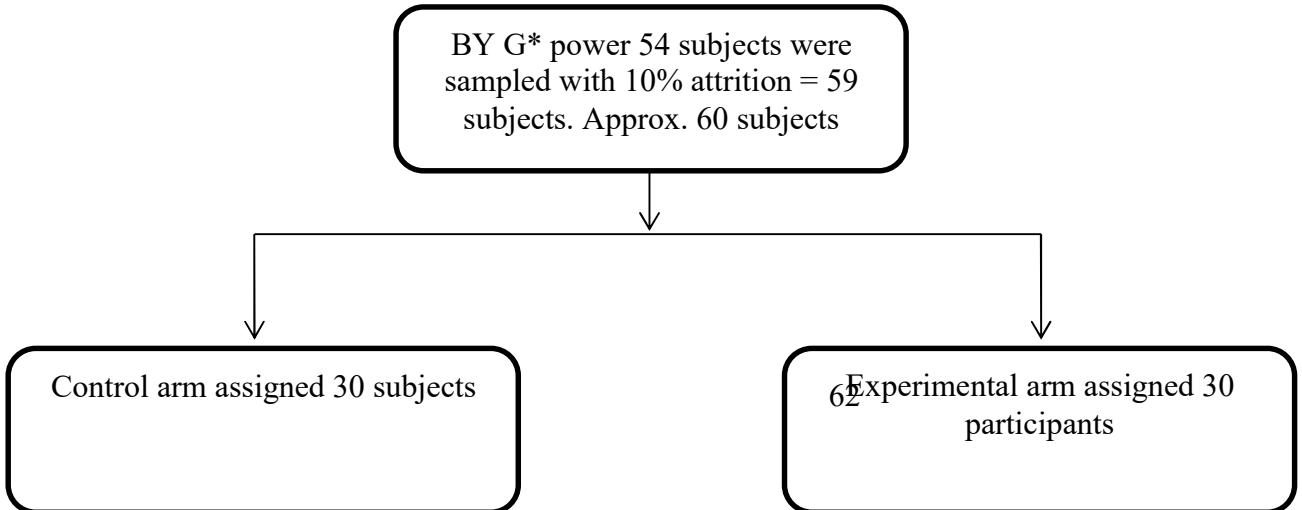


Figure 5: This figure shows the attrition of subjects.

3.7 Data and Information collection

The methods and procedures of data collection are explained in this section.

The study collected data on the following:

• Behavioral aspects (diet, physical activity, tobacco and alcohol consumption),

• Physical measurements (height, weight)

• Metabolic risk factors (Random blood glucose level, blood lipids, triglycerides and LDL, HDL cholesterol, Kidney and Liver function tests)

• Family history • Health screening • Nutrition intake were also taken and recorded.

3.7.1 Data Collection Procedures

3.7.1.1 Blood collection: Baseline blood collection and Post intervention Blood Collection

The researcher, a qualified Medical Dietician, 3 CCC health workers (one clinician and 2 nutritionists) administered questionnaires and two qualified registered Laboratory technologist from Busia County referral did phlebotomy (blood collection). All the clients participating in the study were given SP anti-malarial as per the National malaria control guidelines, and de-wormed using 500gm Mebendazole before the intervention and two weeks to the end of the intervention (60days). Those who were found with severe anemia, malaria, lipidemia, high blood sugar levels, abnormal liver and Kidney function or any other NCDS were referred to the health facility for treatment. In this study there was a washout period of 10 days, which was allowed before the final blood collection.

3.7.1.2 Field laboratory arrangements and procedures

Analysis of blood for Hbs, RBS and urinalysis was done at the Busia County Referral hospital laboratory while (Liver function tests(LFTs), Kidney function tests (KFTs) and Lipid profile were send to Nairobi Align laboratory for analysis. The blood collection /phlebotomy were done at the CCC. Six milliliters of blood was obtained from each client by antecubital venipuncture by a registered medical technologist from the hospital, of this blood sample; determining hemoglobin concentration was done by use of a haemocue. The remainder of the blood will be transferred in an aluminum foil covered tubes measuring 16x100 mm and transported to the laboratory in a cool box with ice packs at about 8 to 10 degrees centigrade for other Biochemical tests as outlined below.

3.7.1.3 Blood sugar Analysis

Random blood sugar
Every study subject's finger was sterilized using alcohol swab, then a lancet was used to prick the finger, a strip was then used to collect blood put in the glucometer. And the reading were read in millimols (mmols)

3.7.1.4 Kidney and Liver function Tests

The assessment of kidney function encompasses a battery of two diagnostic tests. The Albumin to Creatinine Ratio (ACR) and Glomerular Filtration Rate (GFR) are two important measures used in the field of nephrology. Glomerular filtration rate (GFR)

serves as an indicator of renal function and is assessed via a blood test. Glomerular filtration rate (GFR) is a crucial parameter used to ascertain the stage of renal disease.

3.7.1.5 Urinalysis

Urinalysis is a diagnostic procedure that examines the urine for protein and blood. Protein in the urine may be caused by a variety of factors, not all of which are pathological. Urine protein levels are elevated by both infection and vigorous physical activity. A few weeks later, the test may be repeated to determine whether the results are comparable. A subsequent urine sample will be examined within a period of twenty-four hours. The outcomes will indicate the rate at which creatinine, a byproduct, is eliminated from the body. Creatinine is a byproduct of muscular tissue degradation.

3.7.1.6 Serum creatinine test

This test determines whether or not there is an accumulation of creatinine in the blood. Creatinine is typically entirely filtered from the blood by the kidneys. An elevated concentration of creatinine indicates a renal issue. The National Kidney Foundation (NKF) classifies as indicative of a kidney disorder a creatinine level exceeding 1.2 milligrams per deciliter (mg/dL) in women and 1.4 mg/dL in males.

3.7.1.7 Blood urea nitrogen (BUN)

Additionally, the blood urea nitrogen (BUN) test detects waste products. BUN assays quantify nitrogen concentrations in the blood. Urea nitrogen is a byproduct of protein degradation. Nevertheless, elevated BUN levels do not always indicate kidney injury. Some antibiotics and common medications, such as aspirin in high concentrations, can also increase BUN levels. The participant will be queried regarding their regular use of any supplements or medications. Certain substances must be abstained from for several days prior to the examination. BUN levels between 7 and 20 mg/dL are considered normal. A greater value may indicate a variety of health issues.

3.7.1.8 Estimated GFR

This test measures the efficiency with which the kidneys filter detritus. The test calculates the rate by considering variables including age, gender, race, test results (specifically creatinine levels), and age.

Weight and height. A value below 60 milliliters per minute on an area of 1.73 square meters could potentially indicate the presence of kidney disease.

3.7.1.9 Liver Function Test

Liver function tests, which are alternatively referred to as liver chemistry, employ blood measurements of proteins, liver enzymes, and bilirubin to ascertain the condition of the liver. The ALT and AST assays quantify the enzymes secreted by the

liver in response to pathogens or injury. The bilirubin test evaluates the liver's ability to eliminate bilirubin, whereas the albumin test measures its ability to produce albumin. In order to assess the bile duct system of the liver, ALP will be utilized.

3.7.1.10 Lipid Profile Analysis

Triglycerides, HDL, total cholesterol, and triglyceride measurements comprise lipid profiles. Blood samples were obtained subsequent to a nocturnal fast lasting 10–12 hours. This process guarantees the elimination of chylomicrons from plasma. The predominant form of cholesterol found in serum is cholesterol ester. Consequently, the initial stage involves the hydrolysis of cholesterol ester by the enzyme cholesterol ester hydrolase. Cholesterol is subsequently oxidized by cholesterol oxidase, which produces hydrogen peroxide and cholest-4-en-3-one. The quantity of hydrogen peroxide produced is directly correlated with the concentration of serum cholesterol. Its formation of a colored pigment through a reaction with a suitable compound, such as 4-aminoantipyrene (which is catalyzed by peroxidase), serves as an indicator. HDL is commonly quantified as HDL cholesterol subsequent to the precipitation of alternative lipoprotein fractions utilizing polyanions such as heparin sulfate-manganese chloride, dextran sulfate-magnesium chloride, or phospho-tungstate-magnesium chloride. To quantify serum triglyceride, the lipase enzyme is utilized; this enzyme facilitates the conversion of triglyceride to glycerol and free fatty acid. Glycerol is subsequently oxidized to glycerophosphate by glycerokinase. The quantification of glycerophosphate is subsequently accomplished through two processes: its reaction with nicotinamide adenine dinucleotide (NAD), which

produces NADH (absorbs at 340 nm without reaction), or its oxidation by glycerophosphate oxidase enzyme, which yields dihydroxyacetone and hydrogen peroxide. The calculation of plasma LDL values generally employs the Friedewald formula: (Triglyceride/5 minus LDL cholesterol minus HDL cholesterol)

3.7.1.11 Hemoglobin Test

The hemocule was utilized to conduct the tests, and the outcomes were documented for each participant at baseline and after the intervention.

3.7.1. 12 Anthropometry assessment

Human anthropometric measurements were conducted prior to the collection of blood samples. At the CCC, the clients were measured for height using an adult digital weighing scale and a heightometer (the apparatus underwent precision checks).

All protocols for ensuring precise measurements were adhered to, including the weighing of patients while wearing lightweight attire and adjusting elaborate hairstyles. The measurements were taken by the researcher, a certified nutritionist, and a seasoned research assistant. The average of two measurements obtained for each client was recorded. After calculating their weights and heights, BMI was computed.

3.7.1. 13 Dietary Assessments

The pre-tested un-quantified modified food frequency questionnaire, modified 24hrs dietary recall, structured questionnaire was administered to study population with nutrition, health and food security questions.

3.8 Data Collection Tools

A structured questionnaire was used to collect baseline data such as Socioeconomic and demographic characteristics of study participants, food security, dietary practices, record anthropometric data, nutrition and health data. Phlebotomy was done and laboratory forms were used to record results

3.8.1 Data collection and recording of morbidity data

Morbidity data was collected daily during feeding days until the last day of drinking the porridge (60^{th} day). A group of non - communicable diseases, illnesses, (opportunistic infections) was recorded e.g. Hypertension, Diabetes (hyperglycemia hypoglycemia), anemia and patients referred to the study clinician. The monitors in the CCC were given stationery and supplies for carrying out their duties.

3.8.2 Reliability

The researcher utilized Cronbach's alpha, a reliability test that assesses the internal consistency of assessments containing multiple response options. As reliability denotes consistency, it quantifies the consistency or stability of test results. It is the capacity to replicate research or test results. A medical thermometer, for instance, is a dependable instrument that consistently registers the accurate temperature upon utilization. Likewise, a dependable mathematics examination will precisely assess the mathematical acumen of each participant, just as dependable research discoveries are capable of being replicated repeatedly. As an illustration, the Kuder-Richardson 20 can be utilized to assess the internal reliability of a binary test, which consists of correct and incorrect responses.

3.8.3 Validity

Internal validity measures the robustness of the research methods that were employed. Assessing the research's applicability to the "real world" is facilitated by external validity. The external validity of a study is substantial if it can be applied to different contexts. External validity is diminished when the study cannot be duplicated in different contexts. External validity is substantial when the results of your study can be extrapolated to different periods, environments, subjects, and experiments. External validity is diminished when the study cannot be duplicated in different contexts. Internal validity serves as a criterion for assessing the soundness of research, specifically determining whether the procedures followed were accurate. It is proportional to the number of confounding variables included in the experiment. Due to the fact that the intervention portion of

this study is replicable in other CCCs, its external validity is substantial. The study has accounted for confounding variables such as malaria and nematodes that impede nutrient absorption; thus, the internal validity of the research is also substantial.

3.8.4 Quality Assurance

3.8.4 .1 Training of cooks and Health workers (Research Assistants) at the CCC

The training was done in one day, since the same CCC cooks were to be maintained for cooking of the feeds during the study. During the training the following was stressed, portioning of feeds, importance of the study and objectives and sticking onto the procedure, importance of monitoring compliance by PLHIV, recording of absenteeism and morbidity. The CCC provided two monitors, a nutritionist and a clinician. The hospital provided 2 cooks and one nutritionist to support and monitor preparation of the porridge. The cooks were supervised.

3.8.4 .2 Standardization of the feeding regimen

The feeding regimen was first be cooked and standardized in the Hospital kitchen. The feed for the experimental groups was prepared with an aim of giving 100% RDA of the key nutrients in the pumpkin, millet and soya bean flours. In this study the staples were millet 385gms , soya 300gms and pumpkin 300 gms flour per day for 30 PLHIV with NCDs , these was the supplement and standard food (Plumpy Nut) as instructed on the sachet for 30 adults and one extra sachet of plumby -nut was kept aside for every patient to cater for any losses. Each client in the treatment group was given 500 ml of porridge every day in the morning except Saturdays, Sundays and public holidays, while 1 sachet of plumby ‘nut was given to each

client in the control group. The clients in the Treatment group were advised not to eat pumpkin, millet and soya products at home (as eating the products could interfere with the study results). The study participants were advised to feed on normal meals at home.

3.8.4 .3 Benefits of combining Millet, Soya bean and Pumpkin Flours

There is an increase in nutritional content when millet, Soya and pumpkin flours are mixed, especially the essential amino acid - Lysine (Mala etal., 2009)

3.8.4 .4 Justification as to why the product was formulated

The product was formulated for managing NCDs using locally available foods since they are readily available and production is cost effective. The ingredients were chosen because there are gluten free and whole grain consumption is associated with reduced NCDs, diabetes (Lie etal., 2002), cardiovascular (Jacobs etal., 1998) and colon Cancer. Many scientific studies support the observation that consumption of whole grain cereals can protect against diabetes, obesity, constipation, cardiovascular disease, and other lifestyle disorders (Anderson etal.,2003) (Fardet.,2010) (McKevith etal., 2004) (Priebe,. 2008).

3.7.4 .5 Recipe for serving 30 adults - PLHIV with NCDs

Table 1: The ingredients and amounts for serving 30 adults -PLHIV with NCDs

PLUMBY 'NUT = 30 SACHETS	POWER PORRIDGE = 18LITERS
Standard Food	**Treatment Food**
Peanut paste, vegetable oil, powdered milk, powdered sugar, vitamins, minerals	Pumpkin flour = 300gms Soya bean Flour= 385 gms Millet flour = 300gms
1 Sachet - Plumby 'Nut = 92 gms	Sugar = 900gms Sun flower oil = 25 mls
1 sachet per person per day	Water 19 liters I cup = 500mls per person per day of porridge

The porridge was prepared for the 30 clients the cooks served the porridge in designated mugs of 500mls for the treatment group and plumby nut was distributed for the control group by nutritionists, care was taken so that the clients don't take the wrong feeds that were not meant for them this was achieved by using a list to call them out then instructed to sit in a designated place.

3.8.4.6 Nutritive value of Pumpkin (cucurbita maxima) as key ingredient.

The fruit and seed of the pumpkin are rich in calcium, iron, protein, and protein, while potassium, magnesium, zinc, manganese, copper, and sodium are present in varying proportions. Potassium is the elemental mineral with the highest concentration, followed by copper and zinc with the lowest. In general, the seed contains a greater abundance of minerals in

comparison to the pulp. The β-carotene content of the fresh fruit varies from 9.15 to 41.28 µg/g, as determined by fresh weight. Due to their high nutritional value, pumpkins should be promoted, as their efficacy in addressing nutritional deficiency, particularly in Kenya, is underscored by their well-established superior nutritional composition. The increase in nutritive value of food products can be readily observed when pumpkin flour is added (Karanja et al., 2014).

According to the USDA Department of Agriculture - Food Data Central, a serving of pumpkin seeds weighing 28 grams is found to have the following nutrients. The nutritional composition of the food item in question includes 3 grams of carbohydrates, 8.6 grams of protein, 14 grams of fat, and 1.7 grams of dietary fiber. Manganese accounts for 56% of the Daily Value (DV), Copper accounts for 42% of the DV, Magnesium accounts for 40% of the DV, Phosphorus accounts for 28% of the DV, and Zinc accounts for 20% of the DV. Iron constitutes around 14% of the Daily Value (DV). Furthermore, pumpkin seeds are found to possess antioxidants and modest quantities of potassium, riboflavin, and folate..

3.8.4. 7 Nutritional Value for red finger millet (U15)

The seed coat of red finger millet (FMSC) possesses notable advantages due to its composition of polyphenols, arabinoxylans, phytates, and flavonoids. The presence of hypoglycemic, nephroprotective, hypocholesterolemic, and anti-cataractogenic properties of FMSC has been confirmed, thereby providing support for the health claims and proving its potential as a nutraceutical for those with diabetes. This study examines the extraction and nutritional characteristics of FMSC, with a

specific focus on arabinoxylan and polyphenols. The investigation explores the potential health advantages associated with these compounds and their utilization in food compositions. According to the study conducted by Oluwatoyin et al. (2022),

In addition to its nutritional value, millet has several health advantages, such as its ability to regulate blood sugar levels. This is attributed to its low content of simple carbs and high content of complex carbohydrates, rendering it a food with a low glycemic index (GI). This implies that millet has a slower digestion rate compared to conventional wheat flour. Consuming foods with a low glycemic index (GI) might effectively mitigate the postprandial blood glucose surge, hence facilitating improved glycemic control for those with diabetes.

Millet has been found to contribute to enhanced digestive health due to its high content of dietary fiber, encompassing both soluble and insoluble forms. The millet's insoluble fiber is commonly referred to as a "prebiotic," indicating its ability to promote the growth and activity of beneficial bacteria within the gastrointestinal tract. This particular fiber variant also plays a significant role in augmenting the volume of fecal matter, hence mitigating the likelihood of developing colon cancer. The presence of soluble fiber in millet has been found to contribute to the reduction of low-density lipoprotein (LDL) cholesterol levels in the bloodstream, which is recognized as a significant risk factor for the development of atherosclerosis. Soluble fiber undergoes gelation within the gastric environment, facilitating the absorption of cholesterol and enabling its safe elimination from the body.

Several studies have indicated that the consumption of millet has the potential to increase levels of high-density lipoprotein (HDL) cholesterol, commonly referred to as "good" cholesterol, while simultaneously reducing levels of triglycerides.

Cholesterol represents a significant risk factor for the development of heart disease. Regular consumption of millet has been suggested as a potential dietary intervention to promote cardiovascular health.

From a nutritional standpoint, millet has a notable abundance of potassium, a mineral known for its beneficial effects on the proper functioning of the kidneys and heart. Potassium additionally assumes a crucial function in the transmission of nerve signals, facilitating the communication between the brain and muscles. Millet is recognized as a highly beneficial dietary component due to its rich content of essential nutrients such as vitamin A, vitamin B, phosphorus, potassium, antioxidants, niacin, calcium, and iron (WebMD, 2022).

3.8.4.8 Nutritive value of Soya Bean flour

Soybean flour is a nutrient-dense food source that contains a variety of vitamins, minerals, isoflavones, and lecithin. These constituents have been scientifically demonstrated to possess potential health benefits, including the ability to reduce cholesterol levels, prevent cancer, and mitigate the loss of bone mass. Soybean flour is highly suggested for individuals with diabetes, pregnant women, children in the developmental stage, people with cardiac conditions, individuals focused on weight management, and the elderly population. (https://www.fitnigerian.com/nutrition-facts/soybean-flour/, 2023).

3.8.4.9 Nutritive value of Plumby' Nut or Ready to eat Therapeutic Food per 92 grams

Plumpy'Nut or Ready to eat Therapeutic Food an is peanut-based paste in a plastic wrapper, in this study it was used as an active control. The treatment can be provided either in a home setting or at an outpatient facility, such as the Community Care Center (CCC), thereby expanding access to a larger population. The development of a readily consumable therapeutic meal called Plumpy'nut took place during the latter part of the 1990s, as a result of the combined endeavors between research scientist André Briend and Nutriset, a private company specializing in the manufacturing of nourishing items for humanitarian assistance objectives. The product is composed of many elements, including peanut paste, milk powder, vegetable oil, sugar, potassium, magnesium, vitamins, and minerals. Each individual sachet, with a weight of 92 grams, possesses a total energy value of 500 kilocalories.

3.8.4.10 De- worming and treatment of malaria and opportunistic diseases.

All the clients were de-wormed twice at baseline and after intervention, according to the Ministry of Health guidelines for de-worming; the clients were given 500mg of Mebendazole. They were also given malaria Prophylaxis according to the National Malaria Control Council guidelines. Those with severe opportunistic diseases were referred to the CCC for treatment.

The CCC nutritionist maintained a register with the clients names and ticked against their names as the clients received their Porridge, RUTF, medication and managed for compliance.

3.8.11 Procedure for processing the flour for the feeds

The Pumpkins were first washed to remove the soil and any unwanted parts. They were then chipped. After the Chipping, the pumpkin chips and seeds were then dried outside on a canvas for a maximum of eight (8) hours per day for two weeks. When the chips and seeds were dry and crispy they were milled using the local milling machine. The flour is then, weighed, packed, labeled and stored in the kitchen store.

3.8.12 Supply of ingredients for porridge preparation

During the meeting with the Agriculture Extension officer from the Ministry of Agriculture and Livestock, he introduced the farmers to the Researcher for purchase pumpkin, millet and soya. This was done to promote the local farmer. The sugar and sun flower oil were bought from the super market and stored in the kitchen store.

3.8.13 Preparation of the Feeds

The daily activities of the porridge preparation did not interfere with the hospital activities. The cooks used their usual hospital kitchen, mugs for drinking porridge were provided by the researcher. The daily measurements for ingredients were done prior to the cooking day. The monitor supervised the weighing of ingredients. The researcher visited the hospital research area randomly first weekly then after every one week to monitor research activities and to solve problems if any. The cooking started early at 8:00 a.m. and the serving of cooked portion begun one hour to the feeding time i.e. break time 10:30a.m. The

porridge was served at a convenient place at the CCC to allow other services to continue, and the clients (PLHIV) walked in for their portion of porridge at different times. The porridge was served from 8 am to 2pm. The control groups were given their portion of plumby nut.

3.8.14 Monitoring for compliance

The clients walked in at different times to receive their portion of porridge and plumby - nut. The monitors gave the clients their mugs of porridge once they are sitted. In between the feeds other activities were implemented like dietary counseling and training for income generation among others.

Both the nutritionists at the CCC supervised clients for compliance. The nutritionists marked everyday against every Client's name for compliance and kept records for compliance. If any client fell sick or did not finish their feed, all this would be recorded and the reason for non-compliance given. The feed was given 5 days in a week excluding, Saturdays, Sundays and holidays. Compliance was defined as the number of days a particular client received and drank the porridge and plumby- nut. Expressed as a percentage of the total number of potential porridge or plumby - nut days.

3.8.15 Quality Control

The researcher, nutritionists and cooks were ready to record any irregularities as Monitors. The researcher frequently visited the study site three times in a week, then afterwards on monthly basis. The reason for regular visits was to ensure that all the study procedures were followed strictly, solve problems if any and replenish the feeds and any other supplies.

3.9 Pilot Study

3.9.1 Pre- testing of data collection tools/Pilot study

The data collection tools were pretested in Ageng'a dispensary, pre- testing helped to pin point problem areas that needed to be addressed before the actual research, for example to reduce anthropometric measurement error, respondent burden, determine whether respondents are responding to questions correctly, ensured that the order of questions were not influencing the way the respondents interpret and answer them. The researcher also checked how the research assistants articulated the questions and how they administered the questions, for consistency and accuracy. Therefore, pretest is a critical examination of the research instrument(s), pre - test helped to determine if the research questionnaire was proper as a valid and reliable research tool (Converse and Presser 2016).

The Power porridge was subjected to organoleptic test, before the beginning of the intervention.

Table 2: Organoleptic test for the Power Porridge (PROLCARMIV)

No. TESTERS	TASTE	TEXTURE	CONSISTENCY	COLOUR
1	5	5	5	5
2	5	5	5	5
3	5	5	5	5
4	5	4	4	5
5	5	4	4	5
6	5	4	4	5
7	5	4	4	5
8	5	4	4	5
9	5	4	4	5
10	5	4	4	5
11	5	4	4	5
TOTAL SCORE	55	47	47	55
KEY				
TASTE-0-5				
TEXTURE-0-5				
CONSISTENCY-0-5				
COLOUR-0-5				

3.10 Data Analysis and presentation

Table 3: Summary of Data Analysis

Data	Method of Analysis
Objective One: To establish the prevalence of NCDs among PLHIV at the CCC in Busia County referral hospital, Western, Kenya.	Percentages, Mean, Chi-square, P- values
Objective Two: To determine anthropometric measurements among PLHIV with NCD at the CCC in Busia County referral hospital Western, Kenya.	Frequencies, percentages, crude odds ratio, Adjusted Odds ratio, P -values , Confidence Interval, mean, SD, t-test
Objective Three: To assess dietary practices among PLHIV with NCD at the CCC in Busia County referral hospital Western, Kenya.	Frequencies, percentages, crude odds ratio, Adjusted Odds ratio, P -values , Confidence Interval, mean, SD, t-test
Objective Four: To establish a baseline lipid profile, random blood sugar level, hemoglobin level, liver and kidney function of PLHIV with NCDs at the CCC in Busia County referral Western, Kenya.	Frequencies, Percentages, Mean, SD, Correlation, t-test
Objective five: To determine the effect of use of standard food	Descriptive statistics Analysis of Variance, t-test

product and treatment food product among PLHIV with NCDs at the CCC in Busia County referral hospital Western, Kenya.	

3.10.1 Statistical analysis

The data entry was done using Microsoft Excel and analysis done using SPSS version 26 for windows. Descriptive statistics for the biochemical variables i.e. means, standard deviation, standard error, range and median were used. Mean change from baseline to post intervention, was obtained for the control and treatment group.

The t-tests were conducted to assess the differences between the control group and the treatment group. The estimation of the intervention effect and the calculation of the 95% confidence intervals (CI) were conducted based on the observed differences. The data underwent a test to determine if the variances were equal, and the proper significance value (P-value) was utilized. The t-test for paired data was employed to assess the differences between pre- and post-intervention values within each group. P-values less than 0.05 were deemed to be statistically significant.

3.11 Logistical and Ethical Considerations

The ethical approval was obtained from Masinde Muliro University of Science and Technology Institutional Ethical Review Committee (IERC). Approval of the proposal by the Directorate of Postgraduate and permission from the Ministry of Health

from the Chief Health officer of Busia County referral hospital which was the study site. . Finally the clearance and permit issued by the National Council for Science and Technology Institute (NACOSTI) was issued.

3.11.1 Ethical Issue in the research

The researcher devised a document for participants to sign, known as an informed consent form, which outlines the necessary information regarding the study and ensures that participants are fully aware of the nature and purpose of their involvement before providing their consent. Obtaining informed permission from those participating in a study constitutes a significant ethical concern in the realm of research conduct. According to Armiger (year), the term "it means that a person knowingly, voluntarily and intelligently, and in a clear and manifest way, gives his consent" refers to the act of an individual providing their consent with full awareness, voluntary intention, intellectual capacity, and in a lucid and evident manner. The protection of a patient's right to autonomy is achieved through the implementation of informed consent. Additionally, it aims to mitigate instances of compromising the patient's integrity and safeguard individual autonomy and truthfulness. In order for individuals to engage in research freely, it is imperative that they possess adequate information regarding the potential dangers and rewards associated with this research. Subjects must possess an understanding of the potential advantages, whether they pertain to the individual or to the field of scientific inquiry, that may arise from acquiring novel information. Additionally, subjects should be provided with comprehensive information regarding alternative options.

The participants were provided with detailed information by the researcher regarding the measures implemented to ensure the preservation of anonymity and confidentiality. Additionally, the researcher specified a designated individual with whom they could engage in discussions pertaining to the study. The researcher additionally presented a "Non-coercive Disclaimer" that explicitly indicates that participation in the study is voluntary and that there will be no negative consequences for individuals who choose not to participate. The study additionally considered those who have physical, cultural, and emotional obstacles, employing a straightforward language to ensure comprehension among this population. The researcher provided an explanation regarding the ability to withdraw from the study. The Declaration of Helsinki offers guidance by asserting that the welfare of the research subject should consistently take precedence over the interests of society and scientific pursuits. The participants were informed that consent comprises four fundamental components: disclosure, comprehension, competency, and voluntarism.

3.11.1 .1 Beneficence – Do not do harm

According to Treece and Treece (1982), debriefing entails providing a comprehensive explanation of the precise objectives of the study and justifying the partial disclosure of information. Additionally, it is suggested that participants should be encouraged to feel comfortable in order to freely articulate their emotions.

3.11.1.2 Respect for anonymity and confidentiality

Confidentiality and anonymity are research topics that are intimately related to the rights to beneficence, respect for human dignity, and faithfulness. According to the American Nursing Association (ANA), safeguarding anonymity is recommended in cases where the individual's name cannot be associated with their personal comments. The researcher was tasked with upholding a level of confidentiality that surpassed conventional allegiance. The researcher consistently considered the psychological and social ramifications that could arise from a violation of confidence among the individuals. To ensure the protection of participants, it was necessary to provide them with information regarding their rights and employ suitable coding systems in each instance.

3.11.1.3 Respect for privacy

In Kenya, it is policy to keep patient's information confidential, this research collected data at the CCC where privacy and confidentiality was practised. The patients were granted autonomy in determining the timing, scope, and overall conditions surrounding the disclosure or non-disclosure of private information. The researcher reciprocated subjects' refusal to disclose confidential information on the grounds that doing so would constitute an infringement of their privacy. A comprehensive compilation of all feasible precautions taken to safeguard subjects from potential physical, psychological, or social harm throughout the research or subsequent to the dissemination of the findings was detailed in a table that appears on page 51.

3.11.1. 4 Vulnerable groups of people

The current study involved PLHIV, who are considered vulnerable participants. The researcher exercised caution and protection towards the respondents due to the heightened susceptibility they possessed to being duped, coerced, or coerced into participating.

3.11.1.5 Other Considerations

3.11.1.5.1 Interview/questionnaire construction:

The structuring of interviews and questionnaires is crucial in order to gather data that can be effectively interpreted. For instance, it is recognized by researchers that lengthy interviews or surveys have a low likelihood of being completed by participants due to potential weariness, and may also contribute to an increase in gatekeeping.

3.11.1.5.2 Statistics/Data:

Appropriate statistical approaches were employed to ensure the validity of the study results. Conducting research involving vulnerable people has certain problems that can potentially complicate statistical analysis, including issues such as a higher prevalence of missing data and a smaller sample size. The researcher selected statistical methodologies that effectively addressed these problems and yielded valuable outcomes.

3.11.1.5.3 Missing data:

The presence of missing data presents a challenge as it diminishes the ability to identify distinctions and introduces a degree of bias (Palmer, 2004). Although numerous studies encounter randomly missing data, missing data in vulnerable samples is typically not coincidental and is typically associated with alterations in the health condition and level of functionality of the participants.

3.11.1.5.4 Storage of research data

The preservation of research documents, including the medical records of patients who have participated in clinical trials, is mandated by law. Depending on the sort of study, the duration can range from one to twenty years. Consequently, access to secure and protected archive facilities was guaranteed. Due regard must be given to the storage and protection of electronic data.

3.11.1.5.5 Researcher qualifications, training and support; and methods of data collection.

The resources, background, and education that most effectively qualified the researcher to conduct research were known. It was crucial that the researcher was adequately outfitted to ensure participant safety, maintain high-quality data, and ensure methodological consistency at the site.

The CCC, funded by AMPATH, is a secure online collaborative workspace where researchers can work together to solve problems. This includes local recruitment of participants, site-specific consent methods, multiple data collection options for participants, involvement of local support services, centralized training of assistant researchers, systematic monitoring, and support.

3.11.1.5.6 Storage and Transportation of Samples from the field to the Laboratory

An essential component of biological research entails the acquisition and retention of samples in preparation for subsequent examination and analysis. Given the temporal lapse between sample collection and analysis, as well as the propensity for biological samples to degrade over time, it was critical to establish an efficient short-term and long-term storage procedure that maintains sample integrity throughout the process.

3.12 SUMMARY OF ETHICAL CONSIDERATIONS.

Sno.	PRINCIPLE	ETHICAL CONCERN	HOW IT WILL BE RESOLVED
1.	Voluntarism	Participant informed consent.	Participation was fully voluntary. After the participant fully understood the study objectives, and had adequate information that would enable him/her to give informed consent which was obtained in writing and verbally. Those who were unable to write signed by their thumbprints/fingerprints.
2.	Privacy and confidentiality	Questionnaires	Data from the research was shared as codes/serial numbers (not names), codes/serial numbers was be used to represent the study participants to ensure confidentiality. Study design required that questionnaires, documents anthropometric data and bio-data and laboratory or biochemical data of the People Living with HIV (PLHIV)/ Non -

			communicable diseases are handled with confidentiality and interviews were done in enclosed room. Confidential identification numbers were also allocated to every participant.
3.	Confidentiality	Security of the Data	Data was handled with confidentiality and files were labeled with serial numbers for reasons of anonymity. No Names, Identity and any personal information collected were revealed in any report. During the data collection all data was transferred to the Research Coordinator in the evening to be kept on 2 separate external hard drives that were kept in a locked safe, after which questionnaires and data would be transferred to the university once data collection analysis and reporting is over where it will be kept on a secure server for 6 years or more.
4.	Justice/respect rights	Interviewer/respondent gender issues	Address of issues between male/female or female/ male interviews, the Research assistants were trained on the need to be respectful and also culturally sensitivity of the region. Male interviewers were trained on the need to ensure that interviews with female respondents are conducted in a neutral space and where necessary the spouse/ partner is informed of the purpose of the interview. Similarly, female interviewees were advised not to interview male respondents in a secluded setup.
5.	Beneficence/do not do any harm	Respondents Expectations	Expectations of interviewees regarding benefits from the study either by receiving material benefits or other interventions were addressed. This study also does not confer any direct benefits to the Study participants. In addition, the research entailed no cost to the respondent. However, the study findings shall contribute important information to policy makers

			in the Kenyan government, health workers, participants and other stakeholders interested in the provision of services in the management of HIV and Non – Communicable Diseases. This information will be disseminated clearly to the study participants during the consenting process.
6.	Beneficence	Do not do any harm e.g. drawing of blood	Informed consent from the participant Was sought. Qualified laboratory technicians ew blood. The activity was conducted in a health facility, where referral were be done need be. The standard protocols for collecting biochemical Samples were used.
7.	Beneficence	Feedback to respondents	Relevant County-stakeholders in the study County, Busia including study communities will be part of the participants at the dissemination of the research findings workshop which will be held at the research site as a learning process.
8.	Confidentiality/ justice	Reporting of rights violations	Feedback mechanism was anonymous and established so that study participants would have a method to report if there were any perceived violations of their rights in collection of samples and interviews.
9.	Voluntarism/informed consent	Taking of Photographs and videos	Informed consent of the caregivers was adhered to and only used for purposes of the study.

10.	Beneficence	Token for participation in the study	Due to the fact that sample collection took up a considerable portion of the participant's day, porridge/plumby nut was provided to participants.

CHAPTER FOUR

RESULTS

4.1 Introduction

This chapter reviews the results and analysis of the data and findings of the study. The findings are discussed as per the study objectives and also in the light of previous research findings and available literature, in order to identify similarities and differences between this study and previous studies and literature.

4.2 Socio-demographic characteristics of respondents

Table 4.1 illustrates the socio-demographic characteristics of the study participants. In terms of the relationship to the household head, 57.8% of the respondents were the household heads themselves, while 42.2% were the spouse or wife of the head. The sex distribution of respondents indicated that a majority of 62.2% were female, while 37.8% were male. This indicates a higher prevalence of PLHIV with NCDs among females in the study area or higher healthcare-seeking behavior among females than males. In terms of age groups, 53.3% of the respondents were aged 50 years or less, 46.7% were aged 50 years and above. This provides a fair distribution of respondents across both age groups, indicating that NCDs among PLHIV with NCDS in the study area is a concern for both younger and older adults in this population, this is a finding that is similar to the National studies conducted by National AIDS and STI Control Programme (MOH -NASCOP, 2018).

Marital status showed that most of the respondents (66.7%) were married, followed by those who were widowed (26.7%), with a small percentage of single individuals (6.7%). This suggests that married individuals or those who have lost their partners are more

likely to have NCDs, but it could also reflect the general marital status distribution in the local population. Religion-wise, 75.6% of the respondents were Protestant, 20.0% were Catholic, and only 4.4% were Muslim. This could likely be a reflection of the religious demographics in Busia County. In relation to education, most of the respondents had reached upper primary education (55.6%). This was followed by those who had secondary education (22.2%) and college-level education (15.6%). A small minority had lower primary education (2.2%) or had not attended school (4.4%).

The occupational status indicated a high level of unemployment with 73.3% of the respondents being unemployed, while 22.2% were temporarily employed. Only 4.4% fell into the 'not applicable' category. This may reflect a broader socioeconomic issue within this population, potentially impacting health outcomes. Finally, regarding the type of work, the majority were engaged in business (44.4%), followed by casual labor (26.7%), artisan/jua kali (6.7%), and farming (8.9%). A section of respondents (13.3%) fell into the 'not applicable' category. This distribution provides insights into the socioeconomic status of the population and the types of occupations they engage in, which can influence lifestyle, diet, and thus prevalence of NCDs. These demographic details are essential as they provided a contextual understanding of the study population, which can further helped in interpreting the subsequent results and designing future interventions. Further chapters will explore baseline NCD levels, anthropometric measurements, dietary practices, and the impact of different food products on this demographic.

Table 4: Socio demographic characteristics of households

Socio demographic characteristics		**n (%)**
Relation to house hold head	Household head	26 (57.8)
	Spouse/wife	19 (42.2)
Gender	Female	28 (62.2)
	Male	17 (37.8)
Age group, years	50 ≤	24 (53.3)
	>50	21 (46.7)
Marital status	Married	30 (66.7)
	Single	3 (6.7)
	Widowed	12 (26.7)
Religion	Catholic	9 (20.0)
	Muslim	2 (4.4)
	Protestant	34 (75.6)
Level of education	College	7 (15.6)
	Lower primary	1 (2.2)
	Not attended school	2 (4.4)
	Secondary	10 (22.2)
	Upper primary	25 (55.6)
Occupational status	Not applicable	2 (4.4)
	Temporary employed	10 (22.2)
	Unemployed	33 (73.3)
Type of work	Artisan/Jua kali	3 (6.7)
	Business	20 (44.4)
	Casual laborer	12 (26.7)
	Farming	4 (8.9)
	Not applicable	6 (13.3)

Socio-demographic data are presented as n (%) number of participants (percentage)

Table 5 Provides a comparative breakdown of the socio-demographic characteristics of the control and intervention groups, which were given the standard food product and treatment food product respectively. Looking at the relation to the household head, the intervention group had a slightly higher percentage of household heads (31.1%) than the control group (26.7%). However, the control group had a higher percentage of spouses/wives (24.4%) compared to the intervention group (17.8%). In terms of gender, females constituted a larger proportion in the control group (37.8%) compared to the intervention group (24.4%). However, the male representation was the same in both the control and intervention groups (24.4%). The age distribution across the two groups was balanced. The percentage of individuals 50 years or less was identical in both groups (26.7%), and a similar trend was observed for individuals aged 51 years and above, with 24.4% in the control group and 22.2% in the intervention group.

The marital status varied slightly between the two groups. There were more married individuals in the control group (37.8%) than in the intervention group (28.9%). There were more widowed individuals in the intervention group (15.6%) compared to the control group (11.1%). In relation to religious affiliation, there was a higher proportion of Protestants in the control group (40.0%) compared to the intervention group (35.6%). A slightly higher proportion of Catholics were present in the intervention group (11.1%) compared to the control group (8.9%). Educational levels showed that a majority of both groups had upper primary education (26.7% in control and 28.9% in intervention). The intervention group had slightly higher individuals with college-level education (8.9%) compared to the control group (6.7%). Regarding occupational status, a larger proportion of the control group was unemployed (40.0%) compared to the intervention group

(33.3%). There was also a higher number of temporarily employed individuals in the intervention group (15.6%) compared to the control group (6.7%). Finally, for the type of work, the control group had a higher percentage of individuals engaged in business (24.4%) than the intervention group (20.0%). However, the intervention group had a slightly higher percentage of casual laborers (15.6%) than the control group (11.1%).

These comparisons help ensure that the control and intervention groups were reasonably well-matched in terms of socio-demographic characteristics, which is important in reducing potential confounding effects and increasing the validity of the study outcomes. Further analyses will examine the impacts of standard and treatment food products on these groups.

The chi-square analysis was conducted to examine the association between socio-demographic characteristics and the groups (control and intervention). The results revealed that there was no significant difference between the control and intervention groups in terms of their relation to the household head ($P = 0.436$), indicating that both groups had a similar distribution of individuals who were household heads or spouses/wives. In terms of gender, there was a no significant difference observed ($P = 0.098$), the distribution of females and males were similar between the two groups. Furthermore, a significant difference was found in the age group variable ($P = 0.025$), with those aged over 50 years being less compared to those aged 50 and below years and above varied between the control and intervention groups. However, no significant differences were observed in terms of marital status ($P = 0.555$), religion ($P = 0.902$), level of education ($P = 0.816$), occupational status ($P = 0.146$), and type of work ($P = 0.825$) between the two groups. These findings suggest that while there were some

differences in sex and age group, the other socio-demographic characteristics showed similar distributions in the control and intervention groups.

Table 5: Socio-demographic characteristics of control and experimental groups

Socio demographic characteristics		**Study groups**		***P***
		Control	**Intervention**	
		n = 23	**n = 22**	
Relation to house hold head	Household head	12 (26.7)	14 (31.1%)	0.436
	Spouse/wife	11 (24.4)	8 (17.8)	
Gender	Female	17 (37.8)	11 (24.4)	0.098
	Male	6 (13.3)	11 (24.4)	
Age group, years	50 ≤	12 (26.7)	12 (26.7)	**0.025**
	>50	11 (24.4)	10 (22.2)	
Marital status	Married	17 (37.8)	13 (28.9)	0.555
	Single	1 (2.2)	2 (4.4)	
	Widowed	5 (11.1)	7 (15.6)	
Religion	Catholic	4 (8.9)	5 (11.1)	0.902
	Muslim	1 (2.2)	1 (2.2)	
	Protestant	18 (40.0)	16 (35.6)	
Level of education	College	3 (6.7)	4 (8.9)	0.816
	Lower primary	1 (2.2)	0 (0.0)	
	Not attended school	1 (2.2)	1 (2.2)	
	Secondary	6 (13.3)	4 (8.9)	
	Upper primary	12 (26.7)	13 (28.9)	
Occupational status	Not applicable	2 (4.4)	0 (0.0)	0.146
	Temporary employed	3 (6.7)	7 (15.6)	
	Unemployed	18 (40.0)	15 (33.3)	
Type of work	Artisan/Jua kali	1 (2.2)	2 (4.4)	0.825
	Business	11 (24.4)	9 (20.0)	
	Casual laborer	5 (11.1)	7 (15.6)	
	Farming	2 (4.4)	2 (4.4)	
	Not applicable	4 (8.9)	2 (4.4)	

Socio-demographic data are presented as n (%) number of participants (percentage). Data analyzed by Chi-square test. *P*-value is set at 0.05.

4.3 Health and Nutrition Characteristics

Table 6 presents the distribution of different food items consumed by households, separated into four categories: daily, monthly, never consumed, and weekly. The staple porridge was the most commonly consumed food on a daily basis, with 51.1% of the households consuming it daily, followed by Amaranth and Kunde at 62.2% and 57.8% respectively. A significant number of households also consumed White tea, Sukuma wiki, Maize meal, and Sunflower daily (53.3%, 51.1%, 82.2%, and 77.8% respectively). For the monthly consumption category, liver was consumed by 77.8% of households, indicating it was a less frequent food item in these households. Similarly, the traditional white sweet potato and Cassava were consumed monthly by 40.0% of the households, along with big fish, which was consumed monthly by 42.2% of households.

Some food items were reported to be never consumed by certain households. For instance, Kasuku, Chipsy, Malo, and Kimbo were never consumed by over 90% of the households. Green peas were never consumed by nearly half of the households (48.9%). Lastly, for the weekly consumption category, several food items were consumed on a weekly basis by over 50% of households, including whole milk (51.1%), rice (55.6%), papaya (55.6%), and eggs (53.3%). The most consumed food on a weekly basis was beans at 77.8%. Tomatoes and Maize meal were both consumed daily by a substantial majority of the households (82.2%), indicating they were staple foods in this context.

In summary, the results indicate a diverse range of food consumption habits among the households, with certain food items being key staples and others being consumed less frequently or not at all. This food consumption pattern can be crucial in evaluating the nutritional status of the households in the context of managing Non-Communicable

Diseases (NCDs) among People Living with HIV (PLHIV). It also informs potential intervention points for improving the nutritional status of this population.

Table 6: Household food items and their consumption

Food Groups	Daily	Monthly	Never Consumed	Weekly
Main Staples				
Maize meal	37(82)	0(0)	6(13)	2(4)
Rice	7(16)	13(29)	0(0)	25(56)
Traditional white sweet potato	3(7)	18(40)	6(13)	18(40)
Yellow sweet potatoes	8(18)	15(33)	6(13)	16(36)
Cassava	8(18)	18(40)	2(4)	17(38)
Green bananas	4(9)	24(53)	0(0)	17(38)
Pulses				
Beans	8(18)	2(4)	0(0)	35(78)
Soya beans	10(22)	9(20)	15(33)	11(24)
Vegetables				
Carrots	3(7)	22(49)	5(11)	15(33)
Spinach	10(22)	10(22)	0(0)	25(56)
Tomatoes	37(82)	0(0)	0(0)	8(18)
Cabbage	20(44)	12(27)	0(0)	13(29)
Fruit				
Mangoes	4(9)	7(16)	7(16)	27(60)
Papaya	7(16)	8(18)	5(11)	25(56)
Avocado	6(13)	11(24)	0(0)	28(62)
Meat/Fish				
Chicken	8(18)	23(51)	2(4)	12(27)
Small fish	19(42)	5(11)	0(0)	21(47)
Big fish	5(11)	19(42)	2(4)	19(42)
Meat	13(29)	9(20)	2(4)	21(47)

Household food items and their consumption data are presented as n (%) number of participants (percentage)

Food Consumption Score (FCS) (WFP/FAO, 2008) is a proxy for household food security and is designed to reflect the quality of population's diet. To measure the proportion of the target population with an acceptable FCS, household data on the frequency of eight food groups consumed over the previous seven days was collected. The consumption frequencies were then summed and multiplied by the standardized food group weights (see the food groups and corresponding weights on table below). Food consumption score classifies households in to 3 categories namely, poor (<21), borderline (21.5-35) and acceptable (>35). (Table 7)

Table 7: Food consumption score weight

Food Group	**Weight**
Main staples	2
Pulses	3
Vegetables	1
Fruit	1
Meat/Fish	4
Milk	4
Sugar	0.5
Oil	0.5

Table 8 describes the food consumption scores (FCS) of the households, divided into three categories: Poor (<21), Borderline (21.5-35), and Acceptable (>35). The majority of the households (71.9%) fell into the 'Borderline' category with scores between 21.5 and 35. This suggests that a substantial portion of the households had food consumption habits that are neither exceedingly good nor particularly poor. However, it may also

indicate that these households have unstable food consumption patterns, with potential for fluctuation into either 'Poor' or 'Acceptable' categories depending on circumstances such as income, food prices, and seasonal availability.

A notable 21.4% of the households had a 'Poor' food consumption score, indicating that these households might have inadequate access to a diverse and balanced diet, which may contribute to poor nutritional outcomes. This group represents a vulnerable subset of the population and may require targeted interventions to improve their food consumption patterns and hence their overall nutritional status. Only a small fraction of the households, 6.7%, had an 'Acceptable' food consumption score (>35). This suggests that a minimal number of households in this study were consistently consuming a balanced and diversified diet, indicative of good food security status.

These results demonstrate a significant need for interventions to improve dietary diversity and food consumption habits in the population studied, with a particular emphasis on those households falling in the 'Poor' category. For the management of Non-Communicable Diseases (NCDs) among People Living with HIV (PLHIV), dietary practices and nutrition play a crucial role, therefore, these findings can guide the development of suitable strategies to enhance food security and dietary practices among these individuals.

Table 8: Household food consumption scores

Food consumption score (fcs)	**n (%)**
Poor <21	10 (21.4)
Borderline (21.5-35)	32(71.9)
Acceptable >35	3(6.7)

Table 9 presents the baseline food consumption scores (FCS) for both the control and intervention groups, expressed as percentages. Additionally, the Crude Odds Ratio (COR), Adjusted Odds Ratio (AOR), and p-values are included to reflect the initial difference between the two groups and to provide the basis for assessing the effect of the intervention later. In the 'Poor' category, 8.0% of the control group and 13.3% of the intervention group fell into this category. This category serves as the reference group (1.00) for the calculation of odds ratios. In the 'Borderline' category, 37.7% of the control group and 33.3% of the intervention group were included. The Crude Odds Ratio (COR) for this category is 2.22 with a 95% Confidence Interval (CI) ranging from 1.01 to 4.88. This suggests that, before adjusting for any other factors, the odds of being in the 'Borderline' category were over twice as high for the control group as compared to the 'Poor' category. After adjustment for potential confounders, the Adjusted Odds Ratio (AOR) is 1.89 with a 95% CI of 0.86 to 4.14. The *P*-value for this category is 0.073, which suggests that the difference in the odds is not statistically significant at the conventional threshold of 0.05.

In the 'Acceptable' category, 4.4% of the control group and 2.2% of the intervention group were represented. The COR is 1.46 with a 95% CI of 0.61 to 3.47, suggesting that, before adjusting for any other factors, the odds of being in the 'Acceptable' category were 1.46 times higher for the control group compared to the 'Poor' category. After adjustment, the AOR is 1.32 with a 95% CI of 0.55 to 3.17. The *P*-value of 0.524 implies that the difference in the odds is not statistically significant.

This baseline comparison of the control and intervention groups is essential in determining the effect of the intervention later. It shows that, initially, there was no statistically significant difference in food consumption scores between the two groups.

Table 9: Baseline food consumption scores for control and intervention groups

Food consumption score (fcs)	**Control** **n =23**	**Intervention** **n =22**	**COR (95% CI)**	**AOR (95% CI)**	***P***
Poor <21	4(8.0)	6(13.3)	1.00 (ref)	1.00 (ref)	-
Borderline (21.5-35)	17(37.7)	15(33.3)	2.22 (1.01 - 4.88)	1.89 (0.86 - 4.14)	0.073
Acceptable >35	2(4.4)	1(2.2)	1.46 (0.61 - 3.47)	1.32 (0.55 - 3.17)	0.524

COR = crude odds ratio, AOR = adjusted odds ratio, CI = confidence interval. *P*-value represents the statistical significance.

A nutrient analysis based on Recommended Dietary Allowance (RDA) values has been conducted using data on food consumption and RDA values from reputable sources. Specific age and gender groups were identified for analysis, and RDA values for each nutrient of interest were obtained from government health agencies or scientific organizations (WHO's Department of Nutrition for Health and Development). Food consumption data was collected through a Hellen Keller Food Frequency questionnaire. Nutrient calculations were performed using a nutrient database or software to determine the nutrient intake for each individual by matching consumed foods with corresponding nutrient values. The calculated nutrient intake was then compared to the RDA values, and the percentage of RDA met was calculated for each nutrient. The results were interpreted to assess the adequacy or insufficiency of nutrient intake and to identify any potential nutrient deficiencies or excessive intakes.

RDA Values:

Vitamin C: 90 mg, Protein: 55 g, Iron: 15 µg and Calcium: 1000 mg

Table 10 presents the baseline Recommended Daily Allowance (RDA) values for both the control and intervention groups for selected nutrients: Vitamin C, Protein, Iron, and Calcium. The RDA is an estimate of the minimum daily dietary intake of a nutrient that will support good health. For Vitamin C, the control group met 90% of the RDA, while the intervention group met 133.3% of the RDA. This suggests that the intervention group had a higher intake of Vitamin C compared to the control group. In terms of protein, the control group met 118.18% of the RDA and the intervention group met 154.5% of the RDA. Both groups exceeded the recommended intake for protein, with the intervention group having a higher protein intake. For Iron, the control group met 70% of the RDA, while the intervention group met 66.7% of the RDA. Both groups had similar iron intake levels, falling slightly below the recommended intake. Regarding Calcium, both groups had an intake significantly below the recommended levels, with the control group meeting only 0.70% of the RDA and the intervention group meeting only 0.80% of the RDA. This suggests that both groups may have inadequate calcium intake.

Table 10: Baseline RDA values for control and intervention groups

Nutrients	**Control** **% RDA met**	**Intervention** **% RDA met**
Vitamin C	90	133
Protein	118.18	154
Iron	70	66.7
Calcium	0.70	0.80

Note:Data are presented as percentage RDA

Table 11 provides a summary of the nutrient intake data for four key nutrients: Vitamin C, Protein, Iron, and Calcium. The average (mean, M) intake of Vitamin C was 104.18 mg with a standard deviation (SD) of 16.94 mg, indicating a moderate variability in Vitamin C intake among the participants. Protein intake showed a mean of 76.36 grams (g) with a SD of 11.27 g. For Iron, the average intake was 541.33 micrograms (µg), with a standard deviation of 97.27 µg. Iron intake ranged from 390.00 µg to 710.00 µg. Calcium intake averaged 10.11 milligrams (mg), with a standard deviation of 2.44 mg. The range of calcium intake was between 7.00 mg and 15.00 mg.

Table 11: Summary statistics table for nutrients intake

Variable	**M ± SD, n =45**
Vitamin C, mg	104.18 ± 16.94
Protein, g	76.36 ± 11.27
Iron, µg	541.33 ± 97.27
Calcium, mg	10.11 ± 2.44

Note: Data are presented as mean and as standard deviation

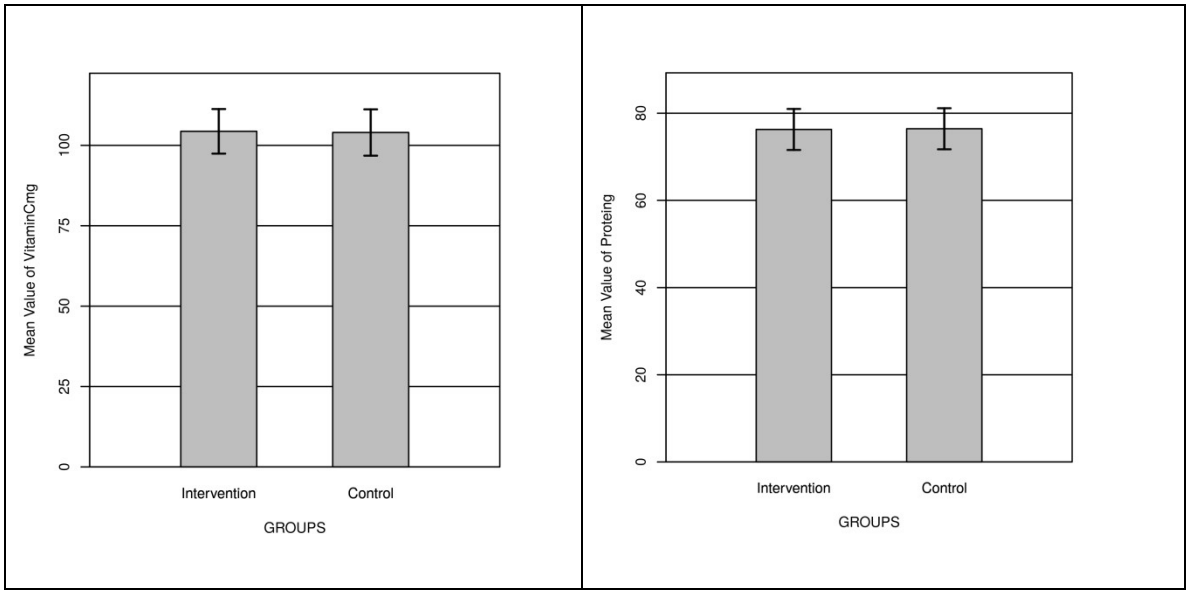
Table 12 presents the results of two-tailed independent samples t-tests comparing nutrient intake between the intervention and control groups. The mean Vitamin C intake was nearly identical between the intervention (M=104.36 mg, SD=16.59) and control groups (M=104.00 mg, SD=17.64). The t-test showed no significant difference between the two groups (t=0.07, *P*=0.944). The small effect size (Cohen's d=0.02) further confirms this. Similarly, for Protein, Iron, and Calcium, the t-tests also showed no significant differences between the intervention and control groups. The p-values for Protein (*P* =0.962), Iron (*P* =0.930), and Calcium (*P* =0.852) were all well above the usual threshold (*P* =0.05) for declaring a statistically significant difference. Furthermore,

the effect sizes (Cohen's d) were also very small for Protein (d=0.01), Iron (d=0.03), and Calcium (d=0.06), suggesting that any differences between the two groups were minimal.

Table 12: Two-Tailed Independent Samples t-Test for nutrients by groups

Variable	Control (n=23) M(SD)	Intervention (n=22) M(SD)	*P*
Vitamin C (mg)	104.00 (17.64)	104.36 (16.59)	0.944
Protein (g)	76.43 (11.53)	76.27 (11.26)	0.962
Iron (µg)	542.61	540.00	0.930
Calcium (mg)	10.04 (2.44)	10.18 (2.50)	0.852
Note. N = 45. Degrees of Freedom for the *t*-statistic, bold is significant			

Note: Data are presented as mean (SD), micro grams, milligrams, *P* -value set at 0.05



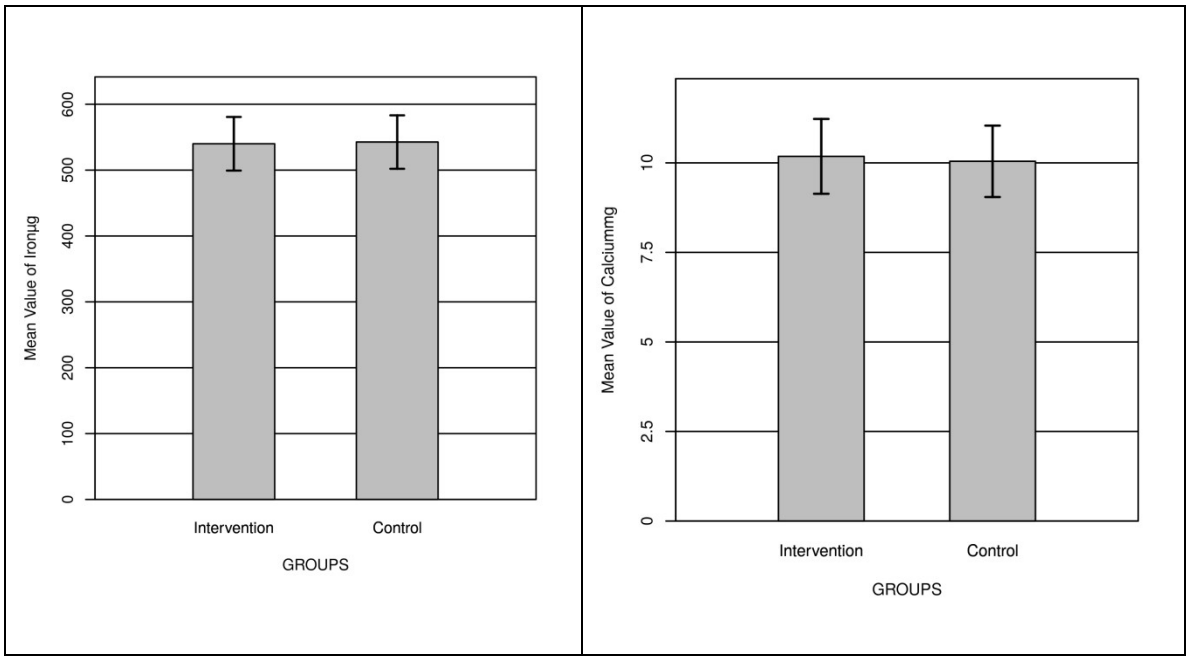


Figure 5: The mean of Nutrients by levels of groups with 95.00% CI

Figure 13 represents the food or dietary intake habits of the participants. It shows that the majority of the participants consumed breakfast, lunch, and supper regularly. Specifically, 93.3% of the participants always ate breakfast, while 6.7% sometimes did. For lunch, 84.4% always ate, while 8.9% never ate lunch, and 6.7% sometimes ate. For supper, an overwhelming 95.6% of participants always ate supper, while a small proportion (4.4%) sometimes did. In contrast, snack consumption habits were more varied among participants. Only 22.2% of participants always ate snacks, while a higher proportion (26.7%) never ate snacks. However, the largest proportion (51.1%) of participants reported eating snacks sometimes. This data could be useful for understanding meal habits and patterns among the participants, which can further aid in understanding their nutritional intake and health outcomes.

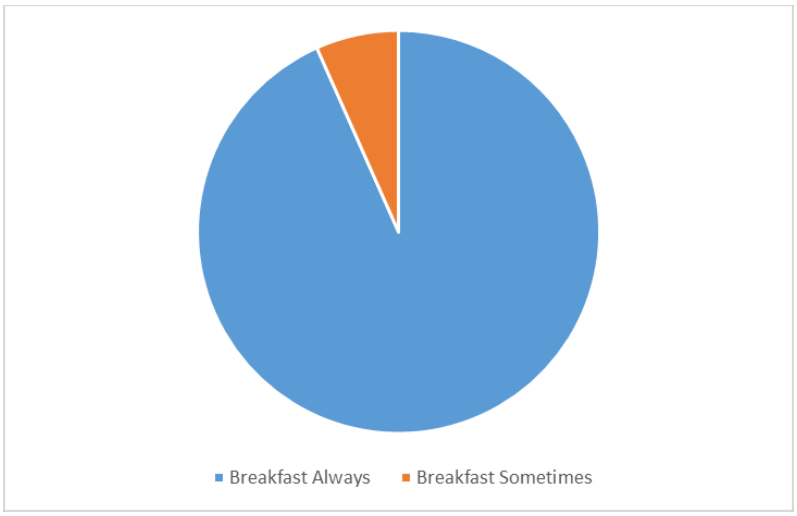


Figure 6a : Food/Dietary intake (Breakfast)

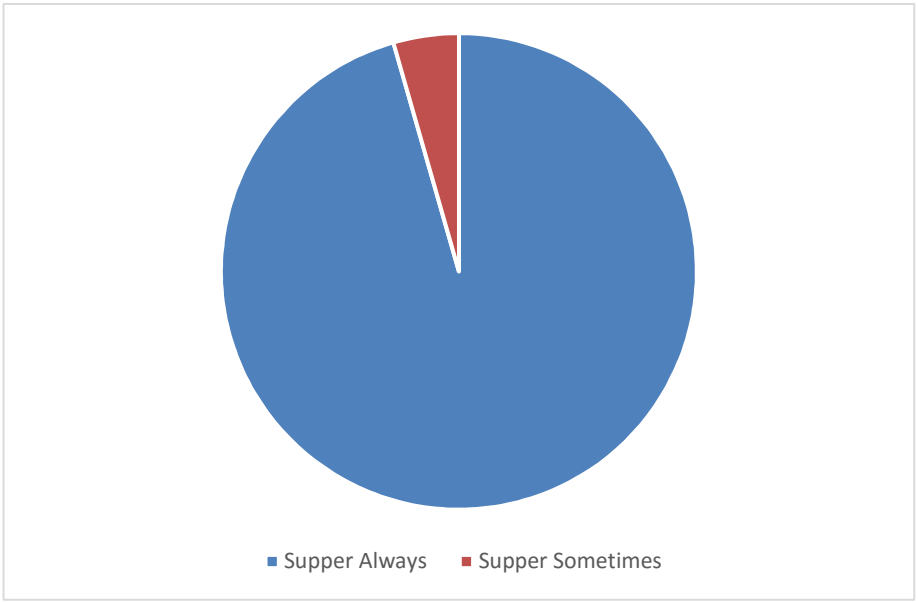


Figure6a: Food/Dietary intake (Supper)

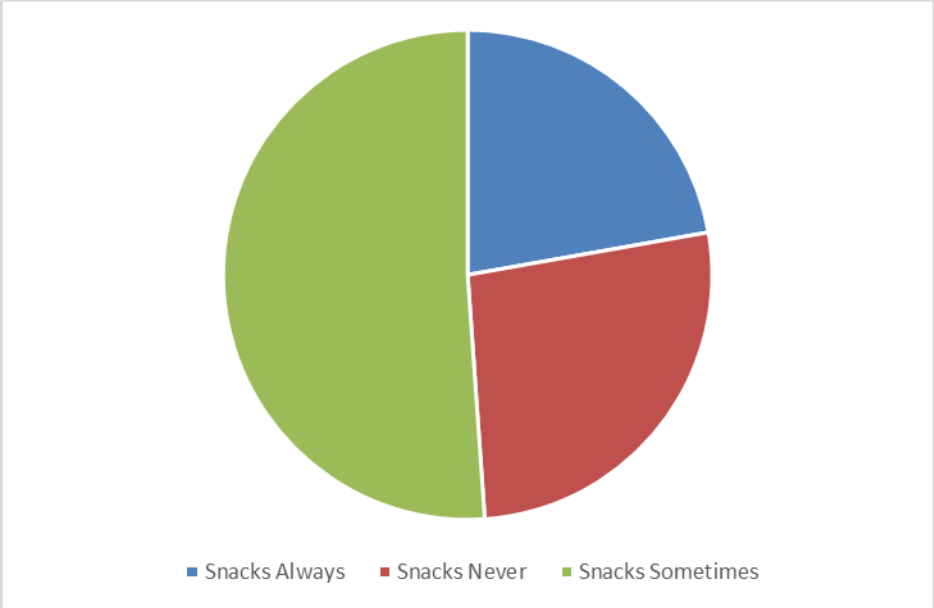


Figure 6 c: Food/Dietary intake (Snacks)

4.4 Anthropometric status of respondents

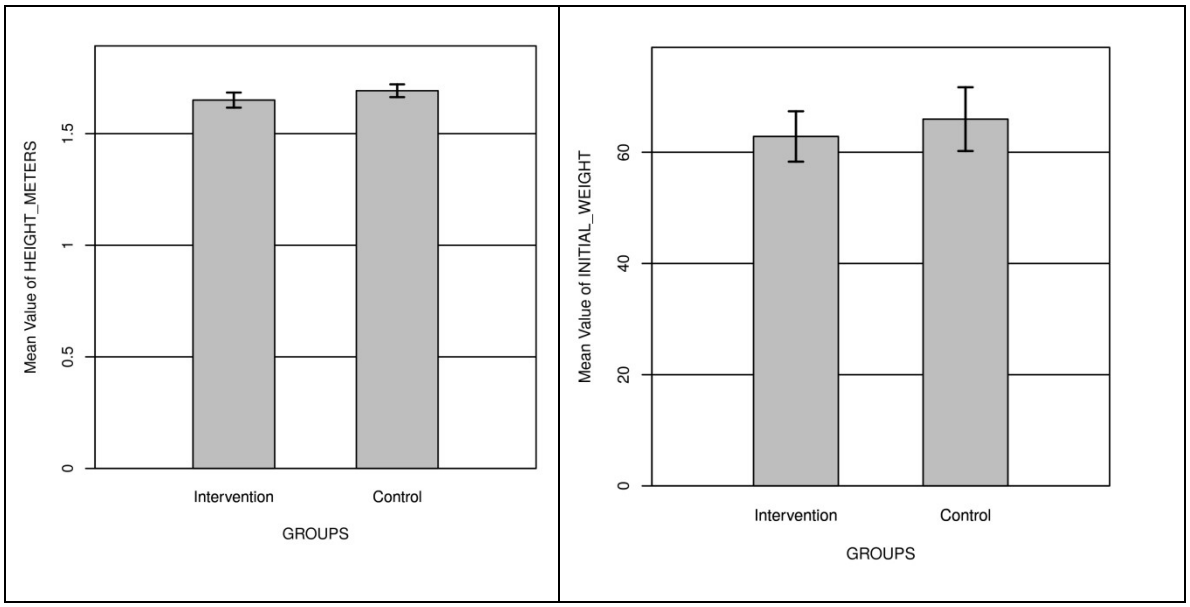
Table 14 shows the results of a two-tailed independent samples t-test comparing the anthropometric parameters between the intervention and control groups. This test determines whether there is a significant difference between the means of these two groups. The mean height of the intervention group was 1.65 meters, compared to 1.69 meters in the control group. The t-test suggests there's no statistically significant difference in height between the two groups ($P = 0.070$), although the P-value is close to the commonly used threshold of 0.05. Similarly, the mean baseline weight of the intervention group (62.84 kg) wasn't statistically significantly different from that of the control group (65.96 kg) ($P = 0.411$). For Post Intervention Weight, the t-test revealed a significant difference in post-intervention weights between the two groups (P = 0.044).

Similarly, the mean post-intervention BMI of the intervention group (24.49) was statistically significantly different from that of the control group (23.98) ($P = 0.041$).

Table 13: Two-Tailed Independent Samples t-Test for anthropometric parameters by groups

Variable	Control M(SD) n=23	Intervention M(SD) n=22	*P*
Baseline Weight (kg)	65.96 (14.03)	62.84 (10.84)	0.411
Post-intervention Weight (kg)	66.07 (13.86)	64.89 (11.32)	**0.044**
Height (m)	1.68 (0.14)	1.68 (0.08)	0.823
Baseline BMI (kg/m²)	23.05 (4.96)	23.08 (3.77)	0.642
Post-intervention BMI (kg/m²)	23.9 8 (3.62)	24.4(6.34)	**0.041**

Note: Data are presented as mean (SD), p-value is set at 0.05



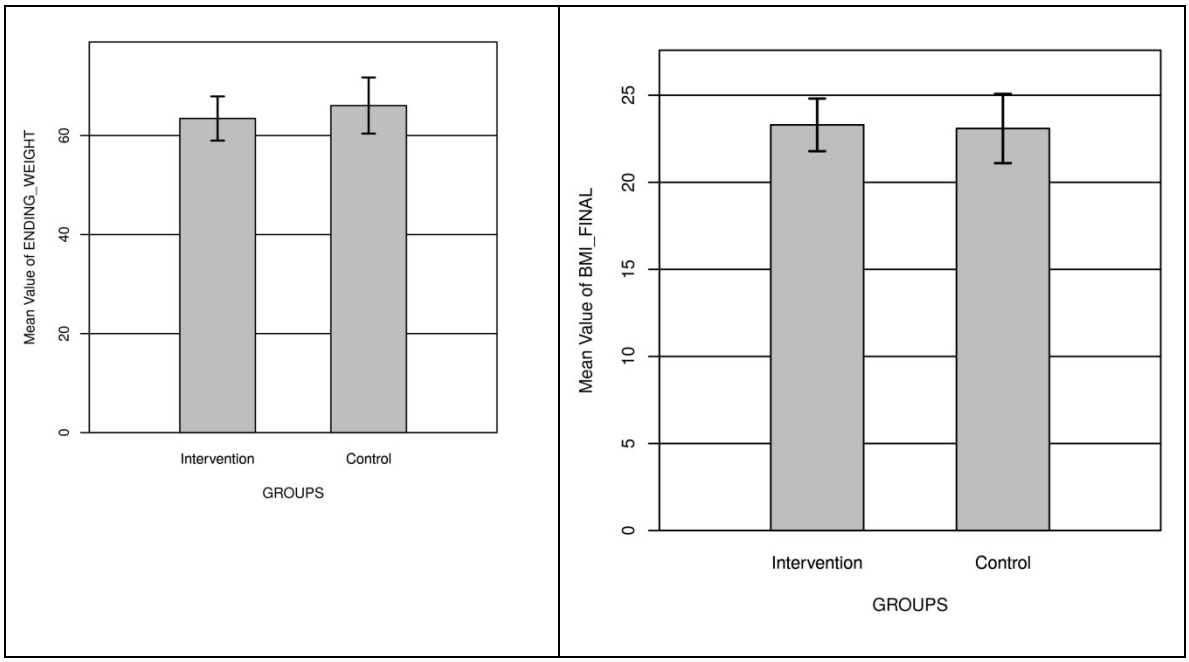


Figure 7. *The mean of anthropometrics by levels of groups with 95.00% CI*

4.5 Morbidity pattern in the study subjects

The medical history of the participants revealed several past and current medical conditions. Hypertension was the most prevalent condition, reported by 73.3% (n=33) of the participants. Arthritis was also notable, affecting 15.6% (n=7) of the respondents. Congenital hearing loss and sickle cell disease were less common, reported by 8.9% (n=4) and 2.2% (n=1) of the respondents, respectively. Regarding medication, the most frequent response was 'None', which constituted 31.1% (n=14) of the participants, indicating that these participants were not on any specific medication at the time of the study. About 26.7% (n=12) of the respondents reported taking Hydrochlorothiazide (Hct2). Other medications reported were Nifedipine by 17.8% (n=8), dietary modification by 13.3% (n=6), Folic acid by 6.7% (n=3), and Septrin by 4.4% (n=2) of the respondents. All participants (100%, n=45) reported not taking any vitamin/mineral/herbal/food supplements. Similarly, none of the participants reported smoking. With regards to

alcohol consumption, a vast majority of the participants (93.3%, n=42) reported not drinking alcohol. Only a small fraction (6.7%, n=3) reported drinking alcohol (Table 15). The medical history data provides a crucial backdrop against which to interpret the impact of the standard and treatment food products on the health of PLHIV with NCDs in this population.

Table 14: Medical history

Medical history		**N (%)**
Please list any past or current medical condition that have or are currently being treated for	Arthritis	7 (15.6)
	Congenital hearing loss	4 (8.9)
	Hypertension	33 (73.3)
	Sickle cell disease	1 (2.2)
List any medication that you are currently taking	Dietary modification	6 (13.3)
	Folic acid	3 (6.7))
	Hydrochlorothiazide (Hctz)	12 (26.7)
	None	14 (31.1)
	Nefidipine	8 (17.8)
	Septrin	2 (4.4)
Do you have any vitamin /mineral/herbal/food supplements	No	45 (100.0)
Do you smoke	No	45 (100.0)
Do you drink alcohol	No	42 (93.3)
	Yes	3 (6.7)

Note: Data are presented as n- number of participants in percentages

Figures 7 :Medical history for control and intervention groups

Upon examining the medical history in the control and intervention groups, there was no significant difference in the prevalence of past or current medical conditions being

treated. Hypertension was the most common condition in both groups, with 40.0% (n=18) in the control group and 33.3% (n=15) in the intervention group. Arthritis was reported by 4.4% (n=2) of the control group and 11.1% (n=5) of the intervention group. Congenital hearing loss was reported by 4.4% (n=2) of each group. Only the control group reported cases of sickle cell disease (2.2%, n=1), with no cases reported in the intervention group. However, the differences in the prevalence of these medical conditions between the two groups were not statistically significant ($p>0.05$).

In terms of medication use, there were no significant differences between the two groups ($p>0.05$). Hct2 was equally common in both groups, reported by 13.3% (n=6) of each group.

Figure 16: The use of dietary modification and Nifedipine were also reported by the same percentage of individuals in each group (8.9%, n=4). Folic acid use was reported only in the control group (6.7%, n=3), and no use was reported in the intervention group. None medication was more prevalent in the intervention group (20.0%, n=9) than in the control group (11.1%, n=5). The usage of Septrin was reported by 2.2% (n=1) of each group. All participants in both the control and intervention groups reported not taking any vitamin/mineral/herbal/food supplements and not smoking.

In terms of alcohol consumption, none of the participants in the intervention group reported drinking alcohol, while in the control group, 6.7% (n=3) reported alcohol use. The difference in alcohol consumption between the groups showed a trend towards significance ($p=0.080$), with the intervention group showing less alcohol consumption (**Figure16).** This information may be relevant in considering the overall health behaviors

and lifestyle of the participants when evaluating the impact of the standard and treatment food products.

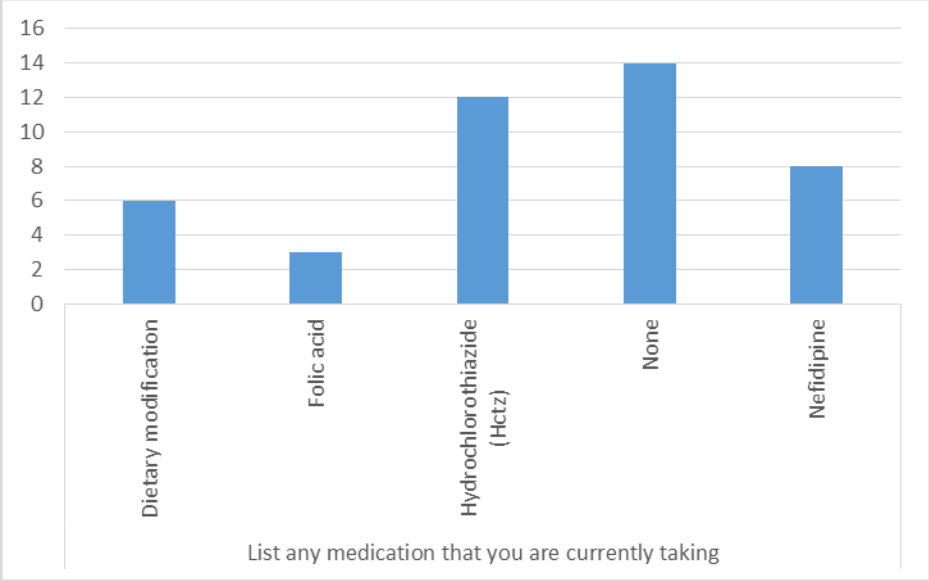


Figure 7 a: List of medication the study subjects were taking

Figure 8: Baseline Health & Nutrition

When participants were asked about their knowledge and experience of Non-Communicable Diseases (NCDs), the majority (86.7%, n=39) did not know a local name for NCDs. Among the 13.3% (n=6) who did, no specific local names were provided in the data. As for the most common NCDs in their community, Hypertension was reported as the most common by a significant majority of the participants (75.6%, n=34), followed by Diabetes (15.6%, n=7) and Malaria (8.9%, n=4). In terms of personal experiences with NCDs, Hypertension again featured prominently, with 71.1% (n=32) of participants reporting having been affected. This was followed by heart disease (8.9%, n=4), Arthritis and Congenital hearing loss (4.4%, n=2 for each), and 11.1% (n=5) reported no NCDs. A total of 44.4% (n=20) of the participants stated they attend a clinic for the treatment of

the aforementioned NCDs, while 55.6% (n=25) do not. Regarding supplementation, only a small fraction of participants (8.9%, n=4) reported receiving any supplementation, while the vast majority (91.1%, n=41) did not. Also, none of the participants reported receiving any food products specifically for their condition in the last 3 months.

The majority of participants reported typically eating three times a day (93.3%, n=42), with a few eating once or twice a day. Almost all participants (95.6%, n=43) consume tea on a regular basis, with a few (4.4%, n=2) also consuming coffee, soda, or energy drinks.

When asked about foods they avoid, Alcohol and fats/oils, as well as sweets, were mentioned by 35.6% (n=16) of participants each. Others reported avoiding specific items such as red meat (11.1%, n=5), fish, and fruits (6.7%, n=3 for each), and bread (4.4%, n=2). Finally, the food items participants reported particularly liking were diverse, with grains, fruits and Kienyeji being preferred by 26.7% (n=12), followed by Ugali vegetable (24.4%, n=11), and vegetables (22.2%, n=10). As for food dislikes, Alcohol and red meat featured prominently, with each being disliked by 20.0% (n=9) of participants. Fast food was also commonly disliked (11.1%, n=5), as were alcohol combined with other foods like Kunde or fast food (8.9%, n=4 for each) (Table 17).

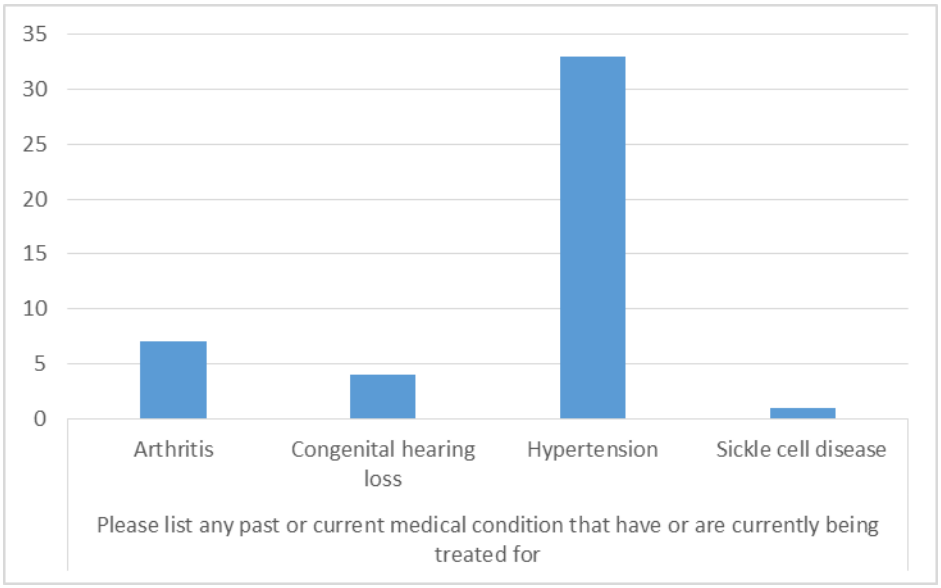


Figure 8 a: The past and current medical conditions that the study subjects were being treated for

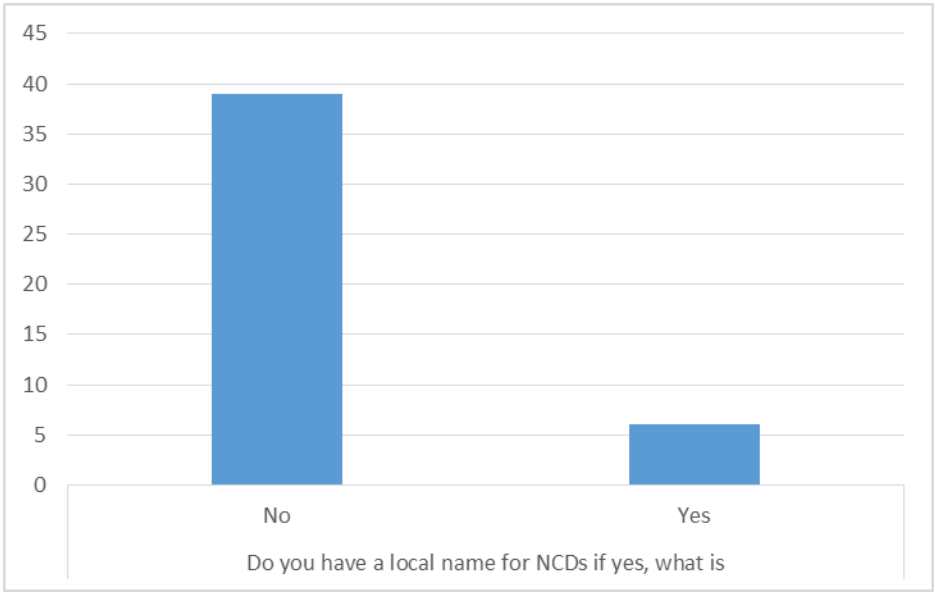


Figure 8 b: Study subject who new NCDs in their local language

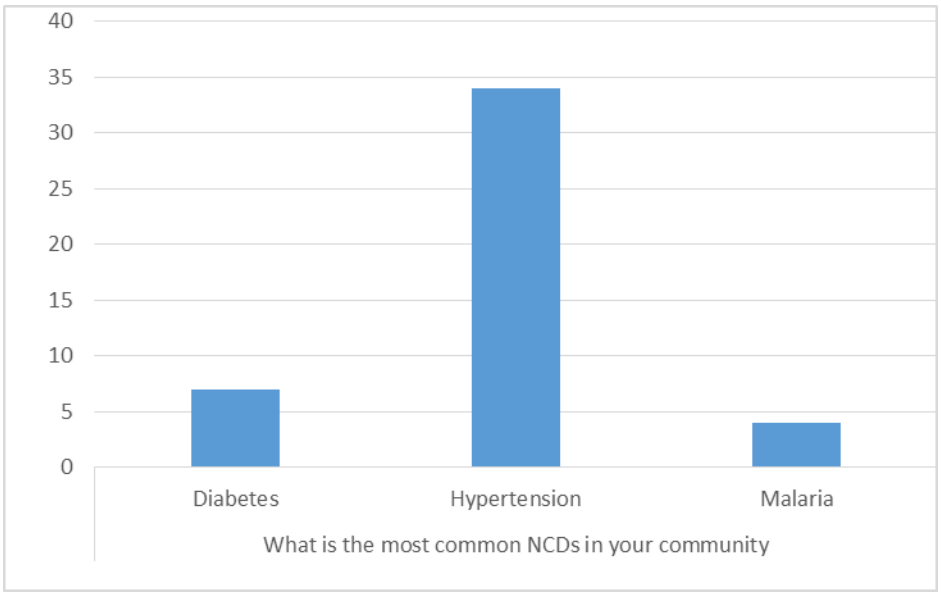


Figure 8 c: The most common NCD in the study community

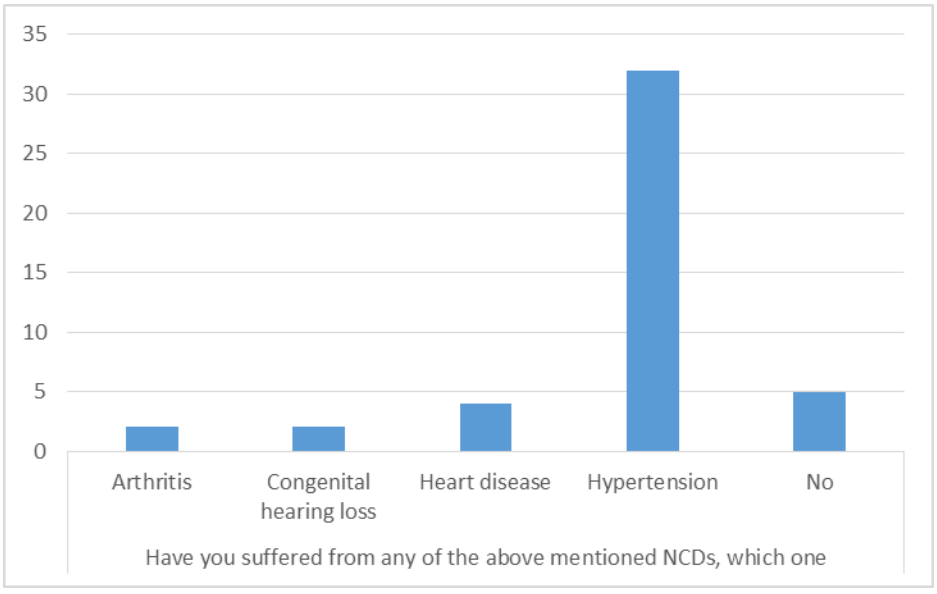


Figure 8 d : NCDs suffered by the study subjects

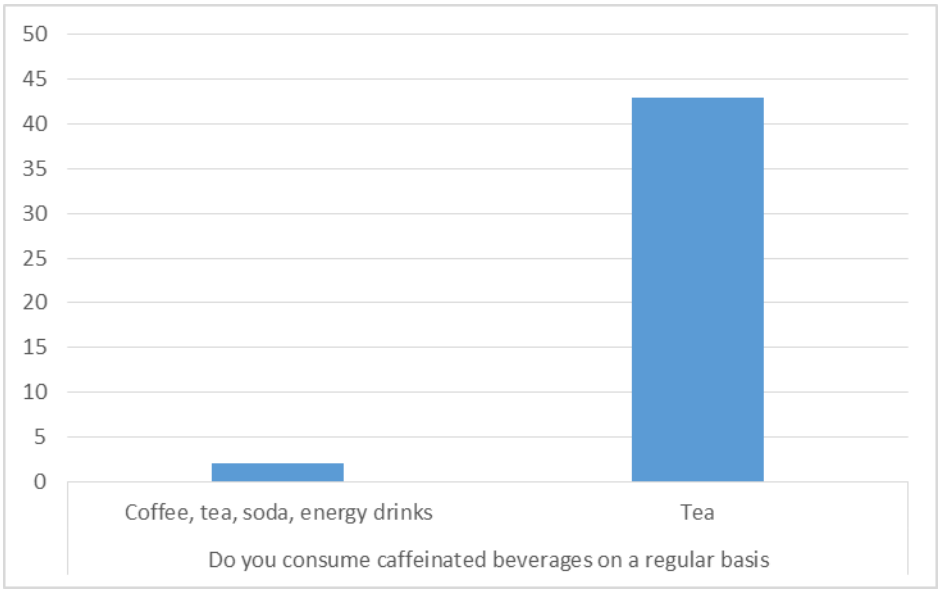


Figure 8 e : Caffeinated beverages consumed by study subjects on regular basis

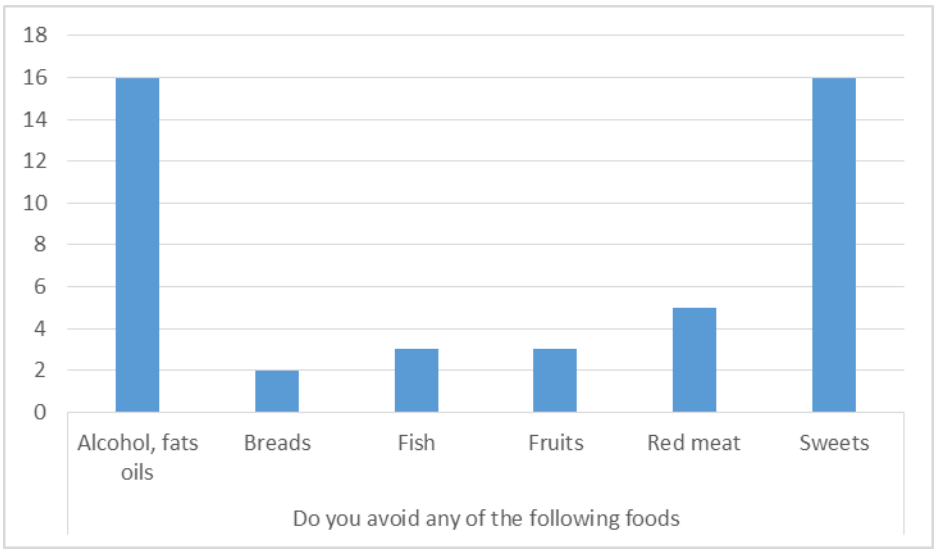


Figure 8 f : Foods avoided by the study subjects

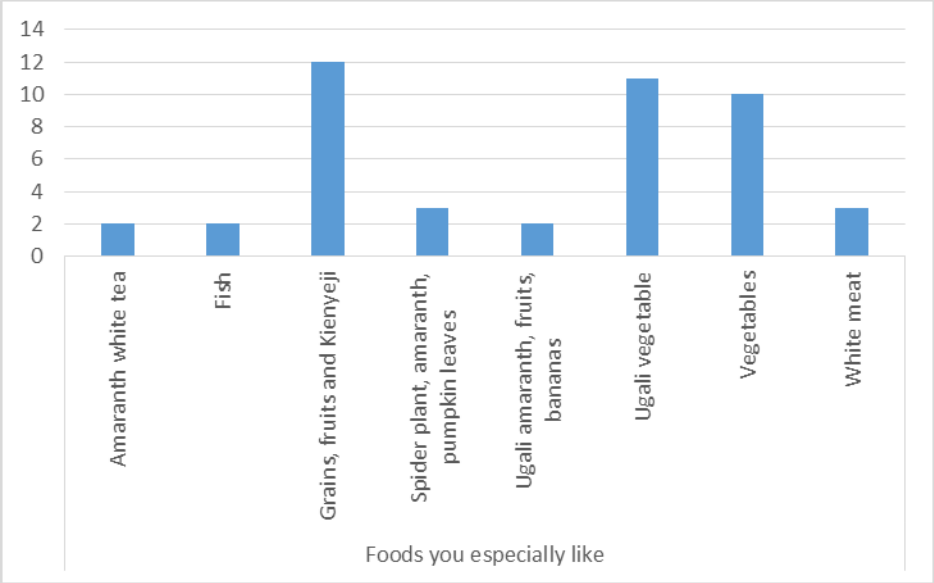


Figure 8 g: Foods liked by the study subjects

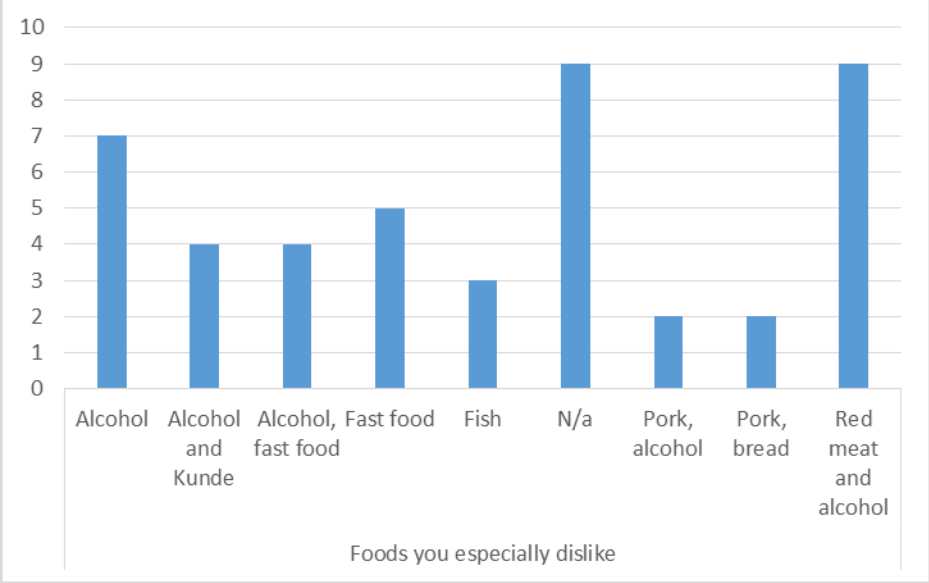


Figure 8 h: Foods disliked by the study subjects

Table 15: Physical Activity History

Concerning physical activity, a considerable majority of the participants reported being physically active (71.1%, n=32), while 28.9% (n=13) were not. When asked about the frequency of physical activity, the most common response was five days a week (35.6%,

n=16), followed by daily activity (17.8%, n=8). A few participants reported physical activity three or four times a week (6.7% and 4.4%, respectively), and a single participant reported being physically active twice a week. However, it is worth noting that 28.9% (n=13) reported no physical activity.

The type of physical activities participants engage in varied. The most commonly reported activity was Farming (17.8%, n=8), followed by Walking (20%, n=9). Other activities mentioned included Cycling, Dancing, Lifting, Running, Weight lifting, and Yoga (each reported by between 2 to 4.4% of participants). 28.9% (n=13) reported no physical activity. In terms of workout intensity, Moderate intensity was the most common (35.6%, n=16), followed closely by Light intensity (31.1%, n=14). Some participants were Inactive (26.7%, n=12), and a small percentage reported engaging in Vigorous weight lifting (6.7%, n=3).

When asked about specific exercises, the responses mirrored the types of physical activities reported, with Farming (17.8%, n=8) and Walking (22.2%, n=10) being the most common. Other exercises like Carrying heavy things, Cycling, Dancing, Jogging, Running, and Yoga were reported by a small percentage of participants. A total of 28.9% (n=13) reported no physical exercise. None of the participants reported smoking cigarettes, aligning with the data from the medical history section. In terms of alcohol consumption, the majority of participants reported they had never consumed alcohol (86.7%, n=39). However, there were a few participants who reported currently consuming alcohol (13.3%, n=6) (Table 18).

Table 16: Physical Activity History

Physical Activity History		**N(%)**
Are you currently physically active	No	13 (28.9)
	Yes	32 (71.1)
How often?	0	13 (28.9)
	2	1 (2.2)
	3	3 (6.7)
	4	2 (4.4)
	5	16 (35.6)
	6	2 (4.4)
	7	8 (17.8)
Type of activities	Cycling	2 (4.4)
	Dancing	2 (4.4)
	Farming	8 (17.8)
	Inactive	13 (28.9)
	Lifting	3 (6.7)
	Running	3 (6.7)
	Walking	9 (20.0)
	Weight lifting	2 (4.4)
	Yoga	3 (6.7)
Please rate the average intensity of your workouts	Inactive	12 (26.7)
	Light	14 (31.1)
	Moderate	16 (35.6)
	Vigorous weight lifting	3 (6.7)
What type of exercise do you do	Carrying heavy things	3 (6.7)
	Cycling	2 (4.4)
	Dancing	2 (4.4)
	Farming	8 (17.8)
	Inactive	13 (28.9)
	Jogging	1 (2.2)
	Running	3 (6.7)
	Walking	10 (22.2)
	Yoga	3 (6.7)
Do you smoke cigarette	No, I have never smoked	45 (100.0)
Do you drink alcohol	No, I have never done alcohol	39 (86.7)
	Yes, currently	6 (13.3)

Note: Data are presented as n= number of participants and percentage activities undertaken

4.6 Laboratory Analysis

Table 19 focuses on the baseline diagnostic tests results for the intervention and control groups. The statistics are derived from Hemoglobin (HB), Random Blood Sugar (RBS), pH (acid-base balance measurement), Specific Gravity (SG - a measure of urine concentration), Leukocytes (LEUK - white blood cells), and Pus Cells (PUSCELLS) readings. (HB), the average level was slightly higher in the intervention group (M = 13.07 SD 2.10) than in the control group (M = 12.96, SD = 1.83). For Hemoglobin the range of HB levels was similar in both groups, from 10.00 to 16.80 for the intervention group and 9.60 to 16.80 for the control group. Random Blood Sugar (RBS) levels averaged slightly lower in the intervention group (M = 3.89, SD = 1.03) compared to the control group (M = 4.14, SD = 0.99). The RBS readings ranged from 2.60 to 6.80 in both groups. The distributions were positively skewed in both groups, indicating a concentration of values at the lower end with a tail extending towards higher values. PH levels, a measure of acid-base balance, were higher on average in the intervention group (M = 6.19, SD = 1.02) than the control group (M = 5.88, SD = 0.83). The range of pH levels was the same in both groups, from 5.00 to 8.50. The Specific Gravity (SG), a measure of urine concentration, was virtually identical in both groups (M = 1.02, SD = 0.007 for intervention and M = 1.02, SD = 0.005 for control), suggesting similar urine concentrations between the two groups. The range was from 1.00 to 1.02 in both groups. Leukocyte (LEUK) levels were similar between the intervention (M = 0.77, SD = 0.40) and control (M = 0.83, SD = 0.65) groups. The range was 0.02 to 2.00 for the intervention group and 0.50 to 3.00 for the control group. The range was 3.00 to 15.00 for the intervention group and 3.00 to 20.00 for the control group. Table 19).

In summary, there were some differences in baseline diagnostic tests results between the intervention and control groups. However, further analysis will be required to determine if these differences are statistically significant.

Table 17: Summary statistics table for baseline diagnostic tests results by groups

Test	Control M(SD), n=23	Intervention M(SD), n=22
HB	12.96 (1.83)	13.07 (2.10)
RBS	4.14 (0.99)	3.89 (1.03)
pH	5.88 (0.83)	6.19 (1.02)
SG	1.02 (0.005)	1.02 (0.007)
LEUK	0.83 (0.65)	0.77 (0.40)
PUSCELLS	4.70 (4.35)	3.77 (2.72)
Note. '-' indicates the statistic is undefined due to constant data or an insufficient sample size. HB: Hemoglobin; RBS: Random Blood Sugar; PH: pH (acid-base balance measurement); SG: Specific Gravity (urine concentration measurement); LEUK: Leukocytes (white blood cells); PUSCELL: Pus Cells		

Table 20 outlines the summary statistics for post-intervention diagnostic test results between the intervention and control groups. The measures presented are Hemoglobin (HB), Random Blood Sugar (RBS), pH (acid-base balance measurement), Specific Gravity (SG - a measure of urine concentration), Leukocytes (LEUK - white blood cells), and Pus Cells (PUSCELLS). For Hemoglobin (Hb), the mean level was slightly higher in the intervention group (M = 13.62, SD = 2.69) compared to the control group (M = 12.69, SD = 1.24). The hemoglobin levels ranged from 9.10 to 18.10 for the intervention group and 9.20 to 15.70 for the control group. The distribution was slightly positively skewed for the intervention group and negatively skewed for the control group.

Random Blood Sugar (RBS) levels were marginally higher on average in the control group (M = 5.96, SD = 1.70) than in the intervention group (M = 5.79, SD = 1.02). The RBS readings ranged from 3.90 to 7.60 for the intervention group and from 3.80 to 12.30 for the control group. The average pH, a measure of acid-base balance, was virtually identical in both groups (M = 6.12, SD = 0.46 for intervention; M = 6.14, SD = 0.36 for control). The range for both groups was from 5.00 to 6.80. Both distributions were negatively skewed, indicating a few lower values.

Specific Gravity (SG), a measure of urine concentration, was also similar in both groups (M = 1.01, SD = 0.005 for both). The SG ranged from 1.01 to 1.02 for both groups. Leukocyte (LEUK) levels were slightly higher in the intervention group (M = 1.89, SD = 0.40) compared to the control group (M = 1.72, SD = 0.42). The LEUK ranged from 1.00 to 3.00 for both groups. Both distributions were positively skewed, with a heavier tail for the intervention group.

Finally, Pus Cells (PUSCELLS) were slightly higher in the intervention group (M = 9.37, SD = 3.80) compared to the control group (M = 8.18, SD = 3.70). The PUSCELLS ranged from 3.00 to 21.00 for the intervention group and from 3.00 to 22.00 for the control group.

In conclusion, post-intervention diagnostic tests results revealed slight differences between the intervention and control groups across the measures. Whether these differences are statistically significant or clinically meaningful will need to be determined through additional statistical testing and expert interpretation.

Table 18: Summary statistics table for post-intervention diagnostic tests results by groups

Test	Control M(SD), n=23	Intervention M(SD), n=22
HB	12.69 (1.24)	13.91 (2.79)
RBS	5.96 (1.70)	5.79 (1.02)
pH	6.14 (0.36)	6.12 (0.46)
SG	1.01 (0.005)	1.01 (0.005)
LEUK	1.72 (0.42)	1.89 (0.40)
PUSCELL	8.18 (3.70)	9.37 (3.80)
Note. '-' indicates the statistic is undefined due to constant data or an insufficient sample size. HB: Hemoglobin; RBS: Random Blood Sugar; PH: pH (acid-base balance measurement); SG: Specific Gravity (urine concentration measurement); LEUK: Leukocytes (white blood cells); PUSCELL: Pus Cells		

Table 18 presents the results of two-tailed independent samples t-tests comparing the post-intervention diagnostic test results between the intervention and control groups. For Hemoglobin (Hb), there was no statistically significant difference between the intervention (M = 13.91 SD = 2.79) and control groups (M = 12.69, SD = 1.24); t (29.19) = 1.48, p = 0.079, d = 0.44. Random Blood Sugar (RBS) levels were also not significantly different between the intervention (M = 5.79, SD = 1.02) and control groups (M = 5.96, SD = 1.70); t (29.19) = -0.40, p = .688, d = 0.12. The pH level showed no significant difference between the intervention (M = 6.12, SD = 0.46) and control groups (M = 6.14, SD = 0.36); t (29.19) = -0.20, p = .839, d = 0.06. The Specific Gravity (SG) did not significantly differ between the intervention (M = 1.01, SD = 0.005) and control

groups (M = 1.01, SD = 0.005); t (29.19) = 0.45, p = .655, d = 0.13. Leukocytes (LEUK) were not significantly different between the intervention (M = 1.89, SD = 0.40) and control groups (M = 1.72, SD = 0.42); t (29.19) = 1.38, p = .176, d = 0.41. Finally, Pus Cells (PUSCELLS) also did not significantly differ between the intervention (M = 9.37, SD = 3.80) and control groups (M = 8.18, SD = 3.70); t (29.19) = 1.06, p = .293, d = 0.32. In summary, none of the post-intervention diagnostic test results showed a statistically significant difference between the intervention and control groups. This indicates that the intervention may not have led to significant changes in these health indicators. However, these findings should be interpreted with caution, as statistical significance does not necessarily equate to clinical significance. Further analyses and studies may be necessary to confirm these results and explore any potential benefits or effects of the intervention.

Table 19: Two-tailed independent samples t-test for post-intervention diagnostic test results by groups

Test	Control (n=23) M(SD)	Intervention (n=22) M(SD)	*P*
HB	12.69 (1.24)	13.91 (2.79)	0.079
RBS	5.96 (1.70)	5.79 (1.02)	0.688
pH	6.14 (0.36)	6.12 (0.46)	0.839
SG	1.01 (0.005)	1.01 (0.005)	0.655
LEUK	1.72 (0.42)	1.89 (0.40)	0.176
PUSCELL	8.18 (3.70)	9.37 (3.80)	0.293
Note. N = 45. Degrees of Freedom for the *t*-statistic = 29.19. *d* represents Cohen's *d.* HB: Hemoglobin; RBS: Random Blood Sugar; PH: pH (acid-base balance measurement); SG: Specific Gravity (urine concentration measurement); LEUK: Leukocytes (white blood cells); PUSCELL: Pus Cells			

Note: Data are presented as mean (SD), p-value set at 0.05

Table 19 presents the results of a two-tailed paired samples t-test comparing the baseline and post-intervention Hemoglobin (Hb) levels within the intervention group. There was elevation of Hb levels following the intervention baseline (M = 13.27, SD = 1.99) vs post-intervention (M = 13.91 SD 2.79), *P* =0.009. This finding indicates that the intervention lead to a significant change in Hb levels within the intervention group from baseline to post-intervention.

Table 20: Two-tailed Paired Samples t-Test for the Difference Between baseline HB and post intervention HB in intervention group

Test	Baseline M(SD), n=23	Post-intervention M(SD), n=22	*P*
Hb	13.07 (2.10)	13.91 (2.79)	**0.009**
Note. N = 22. Degrees of Freedom for the *t*-statistic = 21.			

Note: Data are presented as mean (SD), *P*- value set at 0.5

Table 20 presents the results of a two-tailed paired samples t-test comparing the baseline and post-intervention Hemoglobin (Hb) levels within the control group. There was no statistically significant difference in Hb between baseline (M = 12.96, SD = 1.83) and post-intervention (M = 12.69, SD = 1.24) measurements within the control group; t (22) = 0.73, p = .471, d = 0.15. This finding indicates that the lack of intervention did not lead to a significant change in Hb levels within the control group from baseline to post-intervention. It suggests that without any intervention, the participants' Hb levels remained relatively stable.

Table 21: Two- tailed Paired Samples t-Test for the Difference Between baseline Hb and post intervention Hb in control group

Test	Baseline M(SD), n=23	Post-intervention M(SD) n =23	*P*
Hb	12.96 (1.83)	12.69 (1.24)	**0.471**
Note. N = 23. Degrees of Freedom for the *t*-statistic = 22.			

Note: Data are presented as mean (SD), *P*- value set at 0.5

Table 24 presents the results of a two-tailed paired samples t-test comparing the baseline and post-intervention RBS levels within the intervention group. There was a statistically significant difference in RBS levels between baseline (M = 3.89, SD = 1.03) and post-intervention (M = 5.79, SD = 1.02) measurements within the intervention group; t (21) = -5.94, p < .001, d = 1.27. This finding indicates that the intervention significantly increased RBS levels within the intervention group from baseline to post-intervention. The effect size (Cohen's d = 1.27) suggests a large effect of the intervention on RBS levels.

Table 22: Two- tailed Paired Samples t-Test for the Difference Between baseline RBS and post intervention RBS in intervention group

Test	Baseline M(SD), n=22	Post-intervention M(SD), n=22	*P*
RBS	3.89 (1.03)	5.79 (1.02)	**< 0.0001**
Note. N = 22. Degrees of Freedom for the *t*-statistic = 21.			

Note: Data are presented as mean (SD), *P*- value set at 0.5

Table 22 presents the results of a two-tailed paired samples t-test comparing the baseline and post-intervention RBS levels within the control group. There was a statistically significant difference in RBS levels between baseline (M = 4.14, SD = 0.99) and post-

intervention (M = 5.96, SD = 1.70) measurements within the control group; t (22) = -4.02, $P < 0.0001$, d = 0.84. This result indicates that the RBS levels within the control group significantly increased from baseline to post-intervention, despite the absence of the intervention. The effect size (Cohen's d = 0.84) suggests a large effect.

Table 22: Two- tailed Paired Samples t-Test for the Difference Between baseline RBS and post intervention RBS in control group

Test	**Baseline M(SD), n=23**	**Post-intervention M(SD), n=23**	***P***
RBS	4.14 (0.99)	5.96 (1.70)	**< 0.001**
Note. N = 23. Degrees of Freedom for the *t*-statistic = 22.			

Note: Data are presented as mean (SD), *P*- value set at 0.5

Table 23 presents the summary statistics for baseline laboratory blood chemistry test results by groups, providing information on various biochemical parameters measured among PLHIV with NCDs at the CCC in Busia County referral hospital, Kenya. Total Protein (TP): The mean TP level was 69.42 g/dL (SD = 5.32) in the sample of 43 individuals. Chloride (CL): The mean CL level was 99.56 mmol/L (SD = 4.09). The range of CL levels varied from 88.10 mmol/L to 107.10 mmol/L. Potassium (KT): The mean KT level was 4.16 mmol/L (SD = 0.36). Sodium (NA): The mean Na level was 136.83 mmol/L (SD = 5.85). The range of Na levels varied from 120.70 mmol/L to 144.00 mmol/L. Low-Density Lipoprotein (LDL): The mean LDL level was 2.12 mmol/L (SD = 0.57). Blood Urea Nitrogen (UREA): The mean UREA level was 4.47 mmol/L (SD = 1.47). The range of UREA levels varied from 2.92 mmol/L to 11.26 mmol/L. Triglycerides (TG): The mean TG level was 1.51 mmol/L (SD = High-Density Lipoprotein (HDL): The mean HDL level was 1.54 mmol/L (SD = 0.55). Total

Cholesterol (TC): The mean TC level was 4.20 mmol/L (SD = 0.94). Gamma-Glutamyl Transferase (GGT): The mean GGT level was 44.19 U/L (SD = 29.83). The range of GGT levels varied from 9.90 U/L to 136.60 U/L. Alanine Aminotransferase (ALT): The mean ALT level was 22.06 U/L (SD = 20.49). Aspartate Aminotransferase (AST): The mean AST level was 28.58 U/L (SD = 14.44). Direct Bilirubin (DB): The mean DB level was 3.92 µmol/L (SD = 2.48). Total Bilirubin (TB): The mean TB level was 11.12 µmol/L (SD = 8.73). Albumin (ALB): The mean ALB level was 39.71 g/L (SD = 4.34). The baseline laboratory blood chemistry test results provided valuable insights into the biochemical profile of PLHIV with NCDs at the CCC in Busia County referral hospital, Kenya. These findings will serve as a basis for further analyses and comparisons in the subsequent objectives of the research study.

Table 23: Summary statistics table for baseline laboratory blood chemistry test results by groups

Test	M (SD), n =43
TP, g/L	69.42 (5.32)
Cl, mmol/L	99.56 (4.09)
K, mmol/L	4.16 (0.36)
Na, mmol/L	136.83 (5.85)
LDL, mmol/L	2.12 (0.57)
UREA, mmol/L	4.47 (1.47)
TG, mmol/L	1.51 (0.49)
HDL, mmol/L	1.54 (0.55)
TC, mmol/L	4.20 (0.94)
GGT, U/L	44.19 (29.83)
ALP, U/L	120.40 (57.05)
ALT, U/L	22.06 (20.49)
AST, U/L	28.58 (14.44)
DB, µmol/L	3.92 (2.48)
TB, µmol/L	11.12 (8.73)
ALB, g/L	39.71 (4.34)
Note. '-' indicates the statistic is undefined due to constant data or an insufficient sample size. TP: Total Protein; ALB: Albumin; TB: Total Bilirubin; DB: Direct Bilirubin; AST: Aspartate Aminotransferase; ALT: Alanine Aminotransferase; ALP: Alkaline Phosphatase; GGT: Gamma-Glutamyl Transferase; TC: Total Cholesterol; HDL: High-Density Lipoprotein; TG: Triglycerides; LDL: Low-Density Lipoprotein; UREA: Blood Urea Nitrogen; Na: Sodium; K: Potassium; CL: Chloride	

Note: Data are presented as mean (SD), n=number of participants

Table 24 provides the results of the two-tailed paired samples t-test, which compares the baseline and post-intervention laboratory chemistry test results for different groups. Total Cholesterol (TC): For both the intervention and control groups, there was a significant decrease in TC levels from baseline to post-intervention ($p < .001$). The intervention group showed a mean decrease of 53.83 mmol/L (SD = 5.37) with a large effect size (d = 11.48), while the control group had a mean decrease of 59.76 mmol/L (SD = 5.38) with a similar effect size (d = 12.46). Albumin (ALB): Only the intervention group exhibited a significant difference in ALB levels between baseline and post-intervention ($p = .042$). The mean change in ALB was minimal, with a decrease of 0.03 g/L (SD = 4.27). The effect size (d = 0.46) suggests a small but measurable difference. Total Bilirubin (TB): Similar to ALB, only the intervention group showed a significant difference in TB levels from baseline to post-intervention ($p = .042$). The mean change in TB was also minimal, with a decrease of 0.53 μmol/L (SD = 9.86). The effect size (d = 0.46) indicates a small effect. Aspartate Aminotransferase (AST): The intervention group had a significant difference in AST levels between baseline and post-intervention ($p = .042$). The mean change in AST was 0.62 U/L (SD = 15.31). The effect size (d = 0.46) suggests a small effect. Alanine Aminotransferase (ALT): Similar to AST, the intervention group exhibited a significant difference in ALT levels from baseline to post-intervention ($p = .042$). The mean change in ALT was 2.00 U/L (SD = 16.50), with a small effect size (d = 0.46). Gamma-Glutamyl Transferase (GGT): Only the intervention group showed a significant difference in GGT levels between baseline and post-intervention ($p = .042$). The mean change in GGT was 1.14 U/L (SD = 32.95), indicating a small effect size (d = 0.46). High-Density Lipoprotein (HDL): Both the intervention and control groups

displayed a significant difference in HDL levels from baseline to post-intervention ($p = .042$). The intervention group had a mean decrease of 0.02 mmol/L (SD = 0.53), while the control group had a slightly smaller decrease of 0.01 mmol/L (SD = 0.57). The effect size was small ($d = 0.46$). Triglycerides (TG): Similar to HDL, both the intervention and control groups showed a significant difference in TG levels between baseline and post-intervention ($p = .042$). The intervention group had a mean decrease of 0.02 mmol/L (SD = 0.46), and the control group had a slightly smaller decrease of 0.01 mmol/L (SD = 0.52). The effect size was small ($d = 0.46$). Blood Urea Nitrogen (UREA): Only the intervention group exhibited a significant difference in UREA levels from baseline to post-intervention ($p = .042$). The mean change in UREA was minimal, with an increase of 0.02 mmol/L (SD = 1.82). The effect size ($d = 0.46$) suggests a small effect. Sodium (NA): The intervention group had a significant difference in Na levels between baseline and post-intervention ($p < .001$). The mean change in Na was substantial, with a decrease of 55.65 mmol/L (SD = 33.47), indicating a large effect size ($d = 1.70$). In contrast, the control group had a decrease of 62.38 mmol/L (SD = 9.88) with a considerably larger effect size ($d = 5.91$). Potassium (KT): Both the intervention and control groups displayed a significant difference in KT levels from baseline to post-intervention ($p < .001$). The intervention group had a mean increase of 131.01 mmol/L (SD = 5.41), while the control group had a slightly smaller increase of 133.29 mmol/L (SD = 6.30). The effect size was large for both groups ($d = 24.64$ for intervention and $d = 21.29$ for control). The t-test results provide valuable insights into the changes observed in laboratory chemistry test results between baseline and post-intervention for different

groups. These findings indicate the impact of the intervention on various biochemical parameters and can be further explored and discussed in the thesis.

Table 24: Two-Tailed paired samples t-test for the difference between baseline and post-intervention laboratory chemistry test results by groups

Test	**Groups**	**Baseline M(SD), n=21**	**Post-intervention M(SD), n=22**	***P***
ALB, U/L	Control	40.03 (4.47)	40.05 (4.46)	0.767
	Intervention	39.38 (4.27)	39.41 (4.27)	0.524
TB, U/L	Control	11.28 (7.81)	11.03 (7.86)	0.881
	Intervention	10.96 (9.79)	10.43 (9.86)	0.523
AST, U/L	Control	28.57 (13.98)	28.28 (14.03)	0.774
	Intervention	28.58 (15.23)	27.96 (15.31)	0.**045**
ALT, U/L	Control	25.22 (23.84)	24.27 (24.24)	0.162
	Intervention	18.76 (16.17)	16.76 (16.50)	**0.034**
GGT, U/L	Control	43.53 (27.48)	42.99 (27.57)	0.767
	Intervention	44.87 (32.75)	43.73 (32.95)	0.113
TC, mmol/L	Control	4.37 (0.95)	4.39 (0.95)	0.668
	Intervention	4.02 (0.93)	3.78 (0.94)	**0.041**
HDL, mmol/L	Control	1.57 (0.57)	1.58 (0.57)	0.662
	Intervention	1.51 (0.53)	1.47 (0.53)	**0.038**
TG, mmol/L	Control	1.49 (0.52)	1.50 (0.52)	0.772
	Intervention	1.52 (0.46)	1.54 (0.46)	0.194
UREA, mmol/L	Control	4.33 (1.04)	4.34 (1.04)	0.762
	Intervention	4.61 (1.83)	4.63 (1.82)	0.198
Na, mmol/L	Control	135.48 (6.30)	139.10 (9.88)	**0.001**
	Intervention	136.15 (5.41)	138.80 (8.39)	**0.033**
K, mmol/L	Control	4.19 (0.36)	4.46 (0.37)	0.089
	Intervention	4.14 (0.37)	4.80 (0.42)	**0.008**
Note. N = 22. Degrees of Freedom for the *t*-statistic = 21. *d* represents Cohen's *d.* TP: Total				

Protein; ALB: Albumin; TB: Total Bilirubin; DB: Direct Bilirubin; AST: Aspartate Aminotransferase; ALT: Alanine Aminotransferase; ALP: Alkaline Phosphatase; GGT: Gamma-Glutamyl Transferase; TC: Total Cholesterol; HDL: High-Density Lipoprotein; TG: Triglycerides; LDL: Low-Density Lipoprotein; UREA: Blood Urea Nitrogen; Na: Sodium; K: Potassium; CL: Chloride

Note: Data are presented as mean (SD) , *P*- value set at 0.5

Table 25 provides a summary of the post-intervention blood chemistry test results, split by group. This table includes mean (M), standard deviation (SD), sample size (n), standard error of mean (SEM). The mean values for all tests are similar between intervention and control groups, which might indicate that the intervention had no major impact on these biochemical parameters. The variability (as indicated by the standard deviations) is also similar between the two groups for most tests. However, some tests such as Total Bilirubin (TB), Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), and Sodium (Na) showed a higher standard deviation, indicating higher variability in these measurements.

Table 25: Summary statistics table for post-intervention laboratory blood chemistry test results by groups

Test	Control (n=21) M(SD)	Intervention (n=22) M(SD)
TP	69.56 (5.38)	69.27 (5.37)
ALB	40.05 (4.46)	39.41 (4.27)
TB	11.03 (7.86)	10.43 (9.86)
DB	3.99 (2.20)	3.85 (2.80)
AST	28.28 (14.03)	27.96 (15.31)
ALT	24.27 (24.24)	16.76 (16.50)
ALP	123.27 (60.70)	117.40 (54.23)
GGT	42.99 (27.57)	43.73 (32.95)
TC	4.39 (0.95)	4.08 (0.94)
HDL	1.58 (0.57)	1.53 (0.53)
TG	1.50 (0.52)	1.54 (0.46)
LDL	2.26 (0.66)	1.97 (0.42)
UREA	4.34 (1.04)	4.63 (1.82)
K	4.10 (0.68)	4.50 (0.47)
Na	137.48 (6.30)	136.15 (5.41)
Cl	4.19 (0.36)	4.14 (0.37)

Note. Total Protein; ALB: Albumin; TB: Total Bilirubin; DB: Direct Bilirubin; AST: Aspartate Aminotransferase; ALT: Alanine Aminotransferase; ALP: Alkaline Phosphatase; GGT: Gamma-Glutamyl Transferase; TC: Total Cholesterol; HDL: High-Density Lipoprotein; TG: Triglycerides; LDL: Low-Density Lipoprotein; UREA: Blood Urea Nitrogen; Na: Sodium; K: Potassium; Cl: Chloride

Note: Data are presented as mean (SD).

Based on the results in **Table 26**, which presents the two-tailed independent samples t-test for post-intervention laboratory chemistry test results by groups (intervention and

control), the researcher analyzed the findings as follows: Total Protein (TP): There was no significant difference in TP levels between the intervention and control groups (t = -0.18, p = .858, d = 0.05). The mean TP levels were similar in both groups. Albumin (ALB): There was no significant difference in ALB levels between the intervention and control groups (t = -0.48, p = .630, d = 0.14). The mean ALB levels did not differ significantly between the groups.

Total Bilirubin (TB): There was no significant difference in TB levels between the intervention and control groups (t = -0.23, p = .822, d = 0.07). The mean TB levels were similar in both groups. Direct Bilirubin (DB): There was no significant difference in DB levels between the intervention and control groups (t = -0.18, p = .856, d = 0.05). The mean DB levels did not show a significant difference between the groups.

Aspartate Aminotransferase (AST): There was no significant difference in AST levels between the intervention and control groups (t = -0.07, p = .942, d = 0.02). The mean AST levels were similar in both groups. Alanine Aminotransferase (ALT): There was no significant difference in ALT levels between the intervention and control groups (t = -1.21, p = .233, d = 0.36). The mean ALT levels did not differ significantly between the groups.

Gamma-Glutamyl Transferase (GGT): There was no significant difference in GGT levels between the intervention and control groups (t = 0.08, p = .935, d = 0.02). The mean GGT levels were similar in both groups. (t = -1.12, p = .267, d = 0.34).

Blood Urea Nitrogen (UREA): There was no significant difference in UREA levels between the intervention and control groups (t = 0.66, p = .516, d = 0.19). The mean UREA levels were similar in both groups.

Sodium (Na): There was no significant difference in Na levels between the intervention and control groups (t = 0.74, p = .462, d = 0.22). The mean Na levels did not differ significantly between the groups. Potassium (KT): There was no significant difference in KT levels between the intervention and control groups (t = -0.76, p = .453, d = 0.23). The mean KT levels were similar in both groups. Chloride (CL): There was no significant difference in CL levels between the intervention and control groups (t = -0.42, p = .675, d = 0.13). The mean CL levels did not show a significant difference between the groups.

In summary, most of the laboratory chemistry test results did not exhibit significant differences between the intervention and control groups. However the TC mean (4.39(0.95) for the control group: mean 3.78(0.94) for the intervention group: p=0.017 HDL for the control group mean 1.58(0.57): 1.14(0.53) for the intervention group p=0.036: TG for the control group mean 1.50 (0.50): for the intervention group p= 0.017: mean 1.14: (0.46): LDL mean 2.26(0.66) for the control group: 1.43(0.42): for the intervention group p= 0.041: exhibited a significant decrease.

These findings indicate that the treatment food product provided to the intervention group had an impact on the following tested biochemical parameters; TC, HDL, TG, and LDL, they all showed a decrease. See the table below.

Table 26: Two-tailed independent samples t-test for post-intervention laboratory chemistry test results by groups

Test	**Control M(SD), n=23**	**Intervention M(SD) , n=22**	***P***
TP	69.56 (5.38)	69.27 (5.37)	0.858
ALB	40.05 (4.46)	39.41 (4.27)	0.630
TB	11.03 (7.86)	10.43 (9.86)	0.822
DB	3.99 (2.20)	3.85 (2.80)	0.856
AST	28.28 (14.03)	27.96 (15.31)	0.942
ALT	24.27 (24.24)	16.76 (16.50)	0.233
GGT	42.99 (27.57)	43.73 (32.95)	0.935
TC	4.39 (0.95)	3.78 (0.94)	**0.017**
HDL	1.58 (0.57)	1.41 (0.53)	**0.036**
TG	1.50 (0.52)	1.14 (0.46)	0.071**
LDL	2.26 (0.66)	1.43 (0.42)	**0.041**
UREA	4.34 (1.04)	4.63 (1.82)	0.516
Na	75.10 (9.88)	80.50 (33.47)	0.462
K	137.48 (6.30)	136.15 (5.41)	0.453
Cl	4.19 (0.36)	4.14 (0.37)	0.675

Note. N = 45. Degrees of Freedom for the *t*-statistic = 43. *d* represents Cohen's *d.* TP: Total Protein; ALB: Albumin; TB: Total Bilirubin; DB: Direct Bilirubin; AST: Aspartate Aminotransferase; ALT: Alanine Aminotransferase; ALP: Alkaline Phosphatase; GGT: Gamma-Glutamyl Transferase; TC: Total Cholesterol; HDL: High-Density Lipoprotein; TG: Triglycerides; LDL: Low-Density Lipoprotein; UREA: Blood Urea Nitrogen; Na: Sodium; K: Potassium; CL: Chloride

Note: Data are presented as mean (SD), p- value set at 0.5

The table 27 presents the compliance rate for two groups, Control and Intervention; over a period of 51 days (the intervention is 60 days with 10 days set aside for a wash out

period). The compliance rate is measured in terms of the total number of days attended by participants in each group. The Control group had a compliance rate of 79%, indicating that, on average, participants in this group attended approximately 40.45 out of the 51 days. The maximum attendance for the Control group was 44 days, while the minimum attendance was 22 days. The standard deviation of attendance within this group was 4.01, suggesting some variation in attendance patterns among participants.

On the other hand, the Intervention group exhibited a higher compliance rate of 85%. This indicates that, on average, participants in the Intervention group attended around 43.63 out of the 51 days, which is slightly higher than the Control group. The maximum attendance for the Intervention group was 44 days, and the minimum attendance was 42 days. The standard deviation of attendance within this group was lower compared to the Control group, at 0.61. This suggests that the attendance pattern among participants in the Intervention group was more consistent and less variable.

When considering both groups together, the compliance rate was calculated to be 82.5%. On average, participants across both groups attended approximately 42.07 out of the 51 days. The overall standard deviation of attendance was 3.24, which indicates some variability in attendance patterns among all participants.

Interpreting the results, it can be observed that the Intervention group had a higher compliance rate compared to the Control group. This suggests that the intervention implemented in the Intervention group may have had a positive impact on participant attendance. The lower standard deviation in the Intervention group further supports this interpretation, as it indicates greater consistency in attendance.

Table 27: Compliance rate in day out of a total of 51 days

	Percentage (Mean ± SD)
Control	79 (40.45 ± 4.01)
Intervention	85 (43.63 ± 0.61)
Overall	82.5 (42.07 ± 3.24)
Note: The total intervention days are 60 days; 10 days were set aside for wash - out period before the close out of the feeding intervention.	

Note: Data are presented as mean (SD)

CHAPTER FIVE

DISCUSSION

5.1 Introduction

This chapter interprets and explains the meaning of the analysis of the results. It explains how findings help answer the study questions and objectives. The chapter discusses key findings clearly and concisely, it recommends how the study problem should be solved and places the study in the context of previous studies that were conducted. It also discusses and recommends potential future studies.

The concepts of Health Belief Model were contextualized in this discussion section, study subjects responded to the food and Nutrition intervention as per the HBM constructs; Perceived susceptibility, Perceived severity, Perceived benefits and Perceived barriers and Health Motivation to act according to the what is required for their improved quality of life .

5.2 Socio-demographic characteristics of respondents in Busia County Referral Hospital CCC

The study findings indicate that a high percent of the respondents were females as compared to the males. The highest percentage study population were women, most of them were living with HIV and NCDs, these results are in agreement with the 7th edition AIDS in Kenya reports which found an HIV prevalence rate of eight percent in adult women and four percent in adult men (NACC, 2017). In most parts of the world, men access health services less frequently than women, and this trend is unrelated to differences in need for services (Justine etal., 2019). The results of this study show a less percentage of males as respondents agreeing with Justine's study in 2019. As far as

age is concerned, 53.3% of the respondents were aged 50 years or less, 46.7% were aged 50 years and above, there was a fair distribution of respondents across age groups, indicating that NCDs among PLHIV with NCDS in the study area is a concern for both younger and older adults in this population, this is a finding that is similar to the National studies conducted by National AIDS and STI Control Programme (MOH -NASCOP, 2018). (Gobbens etal., 2018) recommend that health care and welfare professionals should focus in particular on people with a low income and carry out interventions aimed at improving their quality of life, the study subjects are from low and middle socio economics status.

The married in the study were more followed by widows and small percentage of singles. The study also found that the subject's highest educational levels was college while the lowest was lower primary education, however, the results show that, a higher percent of the subjects were of upper primary level followed by secondary, college, lower primary school and those who had not attended school were fewer. The result suggest that education affect the lifestyle choices of the research subjects, this results are supported by previous studies such as one conducted by Kenkel,2000, his study found out that 'education is correlated with the use of preventive health care for adults. In this study unemployment was very high, followed by temporary employed the results suggests that there is a big Socio- economic problem among the subjects that impacts on their health outcomes. HIV and NCDs are known to impoverish and also cause unemployment of those affected or living with these conditions, this study is supported by previous studies as those done by Sithara etal., 2019. The study subjects are mainly business people, followed by casual workers, artisan/Jua Kali and farmers, this distribution of results on

type of work shades light on the socioeconomic, lifestyle and NCDs status of the study population. Furthermore, the results indicate the similar trends per group, the control and the intervention groups. The socioeconomic characteristics of the study groups were quite similar reducing confounding factors and increasing reliability and validity of the study outcomes. (Gobbens etal., 2018)in their study show that the associations of socio demographic factors and quality of life depend on the instruments used to assess quality of life.

5.3 Baseline Nutrition and Health characteristics

To assess dietary practices among PLHIV with NCDs at the CCC in Busia County referral hospital, Kenya, different food items consumed by households belonging to the study subjects were divided into four categories, daily, weekly, monthly, never consumed. Researchers are concerned about the poor nutritional habits in Busia, particularly poor consumption of fish in households; a new study revealed that households in Busia eat ugali and vegetables. (GOK, Marine researchers, 2017). The staple porridge, maize meal and tomatoes were categorized as most commonly consumed on daily basis followed by vegetables (scientific name for Amaranth; A. dubius. Amaranth- Chinese spinach and scientific name for Kunde; Vigna unguiculata (L.)Walp. A significant number consumed white tea on daily basis. The most consumed food on weekly basis was whole milk. Foods that were rarely consumed were categorized as monthly consumed, these were Liver, big fish, white sweet potato and cassava. Some foods in the category of never consumed were fats named Kasuku, Chipsy, Malo and Kimbo. The green peas were never consumed by half of the households of the study population. The nutrition findings outlined above (dietary practices) for the study

subjects fall short of the recommendations of the Kenya National Guidelines for Healthy Diets and Physical Activity (MOH, 2017). Also, Michelle M etal, .2017 indicate that evidence from observational and interventional studies demonstrates the benefits of plant-based diets in treating type 2 diabetes and reducing key diabetes-related macrovascular and microvascular complications.Tthis current study is unique because of the use of PLHIV with NCDs; the design selection also is different from Michelle etal study, yet the subjects benefited in increase of Hb and reduction of cholesterol (HDL, LDL, TC and TG). The benefits of a plant-based diet include promotion of a healthy body weight, increases in fiber and phytonutrients, food-microbiome interactions, and decreases in saturated fat. These results agree with a number of studies done by Jafari S etal., 2018. Chen Z, etal., 2021. Baden MY etal., 2021 and Romanos-Nanclares A etal., 2021.

5.4 Food consumption score

In this study the food consumption score was arrived at by using modified Hellen Keller's food frequency questionnaire. The food consumption score classifies households in three categories namely; Poor (<21), Borderline (21.5-35), and Acceptable (>35). (WFP/FAO, 2008). These study findings indicate that the majority of households of study subjects fell into the borderline category. The majority of the households (71.9%) fell into the 'Borderline' category with scores between 21.5 and 35. This suggests that a substantial portion of the households had food consumption habits that are neither exceedingly good nor particularly poor. However, it may also indicate that these households have unstable food consumption patterns, with potential for fluctuation into

either 'Poor' or 'Acceptable' categories depending on circumstances such as income, food prices, and seasonal availability.

A notable 21.4% of the households had a 'Poor' food consumption score, indicating that these households might have inadequate access to a diverse and balanced diet, which may contribute to poor nutritional outcomes. This group represents a vulnerable subset of the population and may require targeted interventions to improve their food consumption patterns and hence their overall nutritional status. Only a small fraction of the households, 6.7%, had an 'Acceptable' food consumption score (>35). This suggests that a minimal number of households in this study were consistently consuming a balanced and diversified diet, indicative of good food security status.

Therefore, the food consumption results indicate that there is a significant need for interventions to improve dietary diversity and food consumption habits in the population studied, with a particular emphasis on those households falling in the 'Poor' category. For the management of Non-Communicable Diseases (NCDs) among People Living with HIV (PLHIV), dietary practices and nutrition play a crucial role, the Power Porridge was developed with an objective that it may be a suitable strategies to enhance the management of NCDS ,improve food security and dietary practices among the study subjects.

5.5 Baseline Recommended Daily Allowance (RDA) values

The baseline RDA values for both the Control and Intervention groups for selected nutrients, Vitamin C, Protein, Iron and calcium were analyzed. In summary, the control and intervention group met the RDA of the selected nutrients except for calcium in both groups which was below the recommended allowance. Specific age and gender were

identified for analysis and RDA values for each nutrient of interest were obtained from government health agencies or scientific organizations (WHO).

5.6 Food/Dietary Intake:

The data from this study suggests that, supper was the most popular meal of the day followed by breakfast and Lunch, a small percentage ate snacks. In all categories of the day's meals, there were very small percentages that never eat either, breakfast, lunch or dinner. These results indicate that at least none of the participants were sleeping hungry. The food insecurity issues did not present themselves among this study population.

5.7 Anthropometric Status of respondents:

To assess anthropometric measurements and dietary practices among PLHIV with NCDs at the CCC in Busia County referral hospital, Kenya. Data collected from the subjects anthropometric (height, weight, and BMI) measurements indicates that baseline BMI for both groups were similar, but baseline data compared with the post- intervention, the average BMI for the intervention group slightly increased while for the control group remained the same. This is a very interesting finding, since the baseline data indicated that average BMI for both the groups were similar. The increase of the BMI for the intervention group may be attributed to the compliance rate at which the subjects were feeding on the power porridge, this group's compliance rate was slightly higher and consistency was also observed in attendance by the subjects, it could be suggested that in these cohort there is an effect of the power porridge on the subject's weight.

5.7.1 Anthropometric data by groups:

Data from the study for the comparison of anthropometric measurements between the Control and Intervention group, indicates that there was no significant difference in post - intervention groups (Control and Intervention) weights as well as the mean post - intervention groups, BMI of the intervention group was not also statistically significant from that of the control group.

5.8 Morbidity pattern in the study subjects

To establish baseline levels of NCDs among PLHIV at the CCC in Busia County referral hospital, Kenya. Data from the medical history of the study subjects was analyzed and it showed the past and current conditions. Hypertension was identified as the most common NCDs among the study subjects concurring with the results of Divala *et al.,* 2016, other diseases found were Arthritis, Congenital hearing loss and sickle cell disease which was less common. Few respondents were on medication such as Hydrochlorothiazide (HCT2) and Nifedifine for treating hypertension, Septrin an antibiotic and Folic acid vitamin supplementation. Others were being counseled on dietary diversification none of the subjects were on herbal or food supplementation at baseline. As it pertains alcohol, a large percentage of the study subjects responded that were not drinking alcohol and not smoking cigarettes.

5.8 .1 Medical History for control and Experimental groups at baseline

The baseline results showed that there was no significant differences between the two study groups as far as the level of NCDs were concerned. Hypertension was the most

common NCD found in both groups. Other diseases found at a smaller percentage were Arthritis and Congenital hearing loss; however sickle cell disease was only found among the control group. The difference in the prevalence of these medical conditions between the two groups was not significant at the baseline.

5.9 Physical Activity History

The study results showed varied physical activities undertaken by the study subjects, such as cycling, dancing, Farming, weight lifting, running, walking, and yoga. However quite a noticeable percentage of these population were found to be inactive. The noticeable percentage of those who did not do exercise may suggest that NCDs are among these study population. The subjects are PLHIV and are on first line ARVS which are known to bring about the cases of NCDs. Another study needs to be conducted to isolate NCDs caused by ARV side effects and those caused by poor lifestyle in the same population.

5.10 Laboratory Analysis

The laboratory analysis of the following variables Hb, LDL, HDL, TG, DB, AST, ALT, ALB, ALP, TP, urea, creatinine, Na, K and CL, RBS, was conducted at baseline and post-intervention to determine the effect of use of standard food product (Plumby 'Nut) and treatment food product (PROLCARMIV) among PLHIV with NCDs at the CCC in Busia County referral hospital in western region of Kenya. The data were then subjected to statistical tests and the baseline results were compared with the post-intervention results. There was an elevation of Hb levels following the intervention baseline (M = 13.27, SD = 1.99) vs post-intervention (M = 13.91 SD 2.79), P =0.009. This finding indicates that the intervention leads to a significant change in Hb levels within the

intervention group from baseline to post-intervention (HB), the average level was slightly higher in the intervention group (M = 13.07 SD 2.10) than in the control group (M = 12.96, SD = 1.83).

When comparing the baseline and post-intervention RBS levels within the intervention group. There was a statistically significant difference in RBS levels between baseline (M = 3.89, SD = 1.03) and post-intervention (M = 5.79, SD = 1.02) measurements within the intervention group; t (21) = -5.94, $p < .001$, d = 1.27. Therefore more investigations are required to isolate these findings from the side effects of the ARVs or the effect of the standard food, while the findings also suggest that the intervention significantly increased RBS levels within the intervention group from baseline to post-intervention these also require more investigation to rule out the development of diabetes since diabetes mellitus is one of the known complications of hypertension of which is one of the NCDs identified in the study subjects. Certain antiretrovirals such as Atazanavir, Ritonavir, and Tenofovir Disoproxil - fumarate may be associated with altered fat redistribution, dyslipidemia, obesity, high cholesterol dysglycemia, diabetes, and a predisposition to cardiometabolic disease has been shown to increase with cumulative exposure (Tesfaye et al., 2014).

The RBS levels within the control group significantly increased from baseline to post-intervention, despite the absence of the intervention, the results of the two-tailed paired samples t-test, which compares the baseline and post-intervention, also suggest more investigations.

Additional laboratory chemistry test results for the control and experimental groups showed the following; Total Cholesterol (TC): For both the intervention and control

groups, there was a significant decrease in TC levels from baseline to post-intervention ($p < .001$). The intervention group showed a mean decrease of 53.83 mmol/L (SD = 5.37) with a large effect size (d = 11.48), while the control group had a mean decrease of 59.76 mmol/L (SD = 5.38) with a similar effect size (d = 12.46).

Further laboratory chemistry test results suggest that there were no significant differences between the intervention and control groups. However, the TC mean (4.39(0.95) for the control group: mean 3.78(0.94) for the intervention group: p=0.017 HDL for the control group mean 1.58(0.57): 1.14(0.53) for the intervention group p=0.036: TG for the control group mean 1.50 (0.50): for the intervention group p= 0.017: mean 1.14: (0.46): LDL mean 2.26(0.66) for the control group: 1.43(0.42): for the intervention group p= 0.041: all exhibited significant decreases.

These findings indicate that the treatment food product which was plant-based provided to the intervention group may have had a positive impact on the lipid profile of the study subjects. This study is also indicative of the positive gains of the food-based nutrition intervention in the reduction of bad fat such as the variables that were measured in the study subjects. (Leitzmann, 2016) in his study suggests that a high dietary intake of phytochemicals with vegetables, fruits, nuts, legumes, and whole grains is associated with a reduced risk for cardiovascular and other diseases. Research has focused on the possible mechanisms of action of phytochemicals in preventing or treating NCDs, cancer, and heart disease (Miller, 2002).

In recent years the role of some secondary metabolites such as phenols, polyphenols, phenolic, and tannins as protective dietary constituents has become an increasingly important area of human nutrition research. Unlike traditional vitamins, they are not

essential for short-term well-being, but there is increasing evidence that modest long-term intakes can have favorable impacts on the incidence of cancers and many chronic diseases, including cardiovascular disease and Type II diabetes, which are occurring in Western populations with increasing frequency (Crozier, 2007)

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

This chapter will conclude the study by summarizing the key research findings in relation to research objectives and questions as well as the value and contributions. It will also review the limitations of the study and propose opportunities for future research.

6.1 Conclusions

The study aimed to investigate the effect of a food based intervention on the management of NCDs among PLHIV in Busia, the results indicate that the most common NCD among the study subjects is Hypertension, answering the first objective of this study.

Further, findings show that the weight and average BMI for the intervention group increased positively, as the second objective of this study sought to assess anthropometric measurements among PLHIV with NCDs.

Subsequently objective three of the study was answered; the dietary practices of the study population were such that staple porridge, maize meal and vegetables were consumed on daily basis which are not in line with the recommendations of the national guidelines on Healthy diets and lifestyles (MOH, 2017), that recommend consumption of lean meat, fish and seafood, poultry, insects or eggs at least twice a week. Drink fresh milk, fermented milk or yoghurt every day. Use oil or fat in moderation in meals; limit the amount of solid fat. Use fortified oil. The food consumption scores for the study population showed a score of borderline, suggesting that there was degree of unstable food consumption patterns, indicating household food insecurity and poor quality of diet in this study population. There were also a notable percentage of households in the category of poor food consumption score, indicating that these households might have inadequate access to diverse and balanced diet, which without intervention may contribute to poor nutritional outcomes.

Objective four of the study was answered; baseline lipid profile, hemoglobin levels, liver and kidney function were similar at baseline and not significant in both the control and experimental group.

Objective five ; the effect of the Prolcarmiv was analyzed, post intervention results on study variables showed varied results that indicated that the food based nutrition intervention had a positive impact on the quality of life of the study subjects, hence answering to the alternative hypothesis of the study ; the positive effect was the decrease of the LDL,TC, TG levels , the increased Hb levels and BMI, but there was also negative impact such as the elevated RBS levels were seen, requiring more investigative efforts for both control and experimental, further analysis is recommended to isolate whether the ARVS had caused this impact or it was from the food intervention.

Finally, this research sought to examine the effect of food based nutrition intervention on the management of NCDs among PLHIV as a means to establishing an integrated approach towards NCD and HIV care and management. The current research suggests as shown in the results section that supporting PLHIV with Food, Nutrition and Dietetics improves the quality of life and in the long run improves on their nutrition status.

6.2 RECOMMENDATIONS

6.2.1 Recommendations for action

Objective one: To reduce the prevalence of NCDs among the study subjects; the Ministries of Health, Research institutions, Academia, Agriculture and Livestock, Education and Social services are called upon to work with the research subjects, private, bilateral, and multilateral organization in community and Health facilities to solve problems such as unemployment, low education levels, food insecurity to alleviate the problem of HIV and NCDS among the research populations. In this study population, NCDs and HIV were a concern for both younger and older persons, as shown from the socio demographic results. All these problems need urgent attention through multisectoral approach and multifaceted interventions. There is a need of relevant Ministries, Research institutions, the academia, Private, Bilateral and Multilateral

organization with the mandate to develop an integrated and multifaceted system that will provide a model that will be used to standardize and support, education, unemployment, prevention, treatment, and develop health and education policies and laws. Individuals alone, scientists alone, medical providers alone, public health experts alone, will not solve socioeconomic problems intertwined with health problems.

Objective two and three: To alleviate identified dietary practices gaps, resolve the health seeking problems of the study subjects; the Busia County Referral hospital through the CNC office are encouraged to approach the County health management team to strengthen the one stop shop for the PLHIV with NCDs, with an aim of increasing the uptake of services by initiating food, nutrition and dietetics interventions for improving dietary practices among the study subjects, such as frequent nutrition assessments, nutrition education, and biochemical assessments, linked to the community agribusiness initiatives. The CCC health workers and the CHVs are called upon to intensify nutrition education and counseling using Information, education and communication materials. The Busia County Referral Hospital should deliberately link up clinical nutrition services through the CCC, with the community nutrition sensitive agriculture (NSA) in order to increase the demand and the use of Local available foods, nutrient dense foods and income generation for the study population and the communities around the facility.

6.2.2 Recommendations for further research

Objectives four and five: The research recommends that the same study be replicated in other counties with an aim of increasing the feeding days from 60 to 120 (3months) days, to allow the impact of the food products to strongly impact on the Nutritional status of the study population.

Also the future study should embrace modern technology during the preparation and packaging of the treatment food formula.

6.2.3 Recommendations for Practice in Medical Dietetics

Objectives four and five: The research recommends intensified micro – teaching on nutrition and dietetics at the CCC for the staff and the PLHIV with emphasis on Non communicable disease.

Outreach services should be revived to increase uptake of services and reduce malnutrition in the study population and surrounding communities. This can be achieved through networking with the academia and all partners mentioned above.

REFERENCES

Achwoka, D., Waruru, A., Chen, T. et al (2019). Non communicable disease burden among HIV patients in care: a national retrospective longitudinal analysis of HIV treatment outcomes in Kenya, 2003-2013. BMC Public Health 19, 372 (2019)

AHA A Patient's Bill of Rights. Chicago: American Hospital Association, 1975 Alencastro PR, Fuchs SC, Wolff FH, Ikeda ML, Branda ˜o AB, Barcellos NT. Independent predictors of metabolic syndrome in HIV-infected patients. AIDS Patient Care STDS 2011; 25:627–634.

Alvarez C, Salazar R, Galindez J, Rangel F. CastaÃ±eda ML, Lopardo G, Cuhna CA, Roldan Y, Sussman O, Gutierrez G, Cure-Bolt N. Metabolic syndrome in HIV-infected patients receiving antiretroviral therapy in Latin America. Braz J Infect Dis. 2010;14(3):256–63.

American Journal of Educational Research (2020). The influence of teacher-parent collaborative monitoring of school attendance on pupils academic performance in Nyahururu Sub- County -Kenya.Vol.BNo.6,367-375.

ANA (1985) Code of Ethics for Nurses. Encyclopedia of Nursing & Allied Health. Available at: www.enotes.com/nursing encyclopedia/ code-ethics-nurses.Acessed on 1-7-2010. 23.

Baden MY, Shan Z, Wang F, Li Y, Manson JE, Rimm EB et al. Quality of plant-based diet and risk of total, ischemic, and hemorrhagic stroke. Neurology. 2021;96(15):e1940–e1953. doi:10.1212/ WNL.0000000000011713.

Bloomfield GS, Alenezi F, Barasa FA, Lumsden R, Mayosi BM, Velazquez EJ. Human Immunodeficiency Virus and Heart Failure in Low- and MiddleIncome Countries. 2015;3:579–90

Brown TT, Cole SR, Li X, Kingsley LA, Palella FJ, Riddler SA, et al. Antiretroviral therapy and the prevalence and incidence of diabetes mellitus in the multicenter AIDS cohort study. Arch Intern Med. 2005;165(10):1179–84

Chen Z, Drouin-Chartier JP, Li Y, Baden MY, Manson JE, Willett WC et al. Changes in plant-based diet indices and subsequent risk of type 2 diabetes in women and men: three US prospective cohorts. Diabetes Care. 2021;44(3):663–71. doi:10.2337/dc20-1636.

Chhoun et al. Non-communicable diseases and related risk behaviors among men and women living with HIV in Cambodia: findings from a cross-sectional study International Journal for Equity in Health (2017) 16:125 DOI 10.1186/s12939-017-0622-y

Converse, Presser. Social science methods. (PsycINFO Database Record (c) 2016 APA, all rights reserved).

De Paoli MM, Manongi R, Klepp K-I. 2004. Factors influencing acceptabilityof voluntary counselling and HIV-testing among pregnant women in Northern Tanzania. AIDS Care 16: 411–25.

Deeks SG, Phillips AN. HIV infection, antiretroviral treatment, ageing, and non-AIDS related morbidity. Bmj. 2009;338:a3172.

Deeks SG. Immune dysfunction, inflammation, and accelerated aging in patients on antiretroviral therapy. Top HIV Med 2009; 17:118–123.

Dillon DG, Gurdasani D, Riha J, Ekoru K, Asiki G, Mayanja BN, et al., African Partnership for Chronic Disease Research (APCDR). Association of HIV and ART with cardiometabolic traits in sub-Saharan Africa: a systematic review and meta-analysis. Int J Epidemiol 2013; 42:1754–1771. [PubMed: 24415610]

Divala OH, Amberbir A, Ismail Z et al. 2016. The burden of hypertension, diabetes mellitus, and cardiovascular risk factors among adult Malawians in HIV care: consequences for integrated services. BMC Public Health 16: 1243

Edwards JK, Bygrave H, Van den Bergh, Kizito W, Cheti E, Kosgei RJ et al. HIV with non-communicable diseases in primary care in Kibera, Nairobi, Kenya: characteristics and outcomes. Trans R Soc Trop Med Hyg. 2015;109(7):440-6

Eugenin EA, Morgello S, Klotman ME, Mosoian A, Lento PA, Berman JW, et al. Human immunodeficiency virus (HIV) infects human arterial smooth muscle cells in vivo and in vitro: implications for the pathogenesis of HIV-mediated vascular disease. Am J Pathol. 2008;172(4):1100–11.

Farahani M, Vable A, Lebelonyane R, Seipone K, Anderson M, Avalos A, et al. Outcomes of the Botswana National HIV/AIDS treatment programme from 2002-2010: a longitudinal analysis. Lancet Glob. Health. 2014:2(1):e44-50

Faul, Erdfelder, Buchner, & Lang, 2009. Statistical Power Analyses Using G*Power 3.1: Tests for Correlation and Regression Analyses.

Freiberg MS, Chang CC, Kuller LH, Skanderson M, Lowy E, Kraemer KL, Butt AA, Goetz MB, Leaf D, Oursler KA, Rimland D. HIV infection and the risk of acute myocardial infarction. JAMA Intern Med. 2013;173(8):614–22.

Freiberg MS, Kraemer KL. Focus on the heart: alcohol consumption, HIV infection, and cardiovascular disease. Alcohol Res Health. 2010;33:237–46.

Friis-Møller N, Thiebaut R, Reiss P, Weber R, D'Arminio Monforte A, De Wit S, El-Sadr W, Fontas E, Worm S, Kirk O, Phillips A. Predicting the risk of cardiovascular disease in HIV-infected patients: the data collection on adverse effects of anti-HIV drugs study. Eur J Cardiovasc Prev Rehabil. 2010; 17(5):491–501.

Fumaz CR, Munoz-Moreno JA, Molto ~ ´ J et al. 2008. Sustained antiretroviral treatment adherence in survivors of the pre-HAART era: attitudes and beliefs.

Gouda HN, Charlson F, Sorsdahl K, et al.. Burden of non-communicable diseases in sub-Saharan Africa, 1990-2017: results from the global burden of disease study 2017. *Lancet Glob Health* 2019;7:e1375–87. 10.1016/S2214-109X(19)30374-2 [PubMed] [CrossRef] [Google Scholar]

Helen A.E,Kassa D, Befekadu B,Mengistu M. Challenges to *nutrition* management among patients using *antiretroviral* therapy in primary health centers in Adis Ababa Ethiopia

Islam FM, Wu J, Jansson J, Wilson DP. Relative risk of cardiovascular disease among people living with HIV: a systematic review and meta-analysis. HIV Med. 2012;13(8):453–68.

Jafari S, Hezaveh E, Jalilpiran Y, Jayedi A, Wong A, Safaiyan A et al. Plant-based diets and risk of disease mortality: a systematic review and meta-analysis of cohort studies. Crit Rev Food SciNutr. 2021:1–13. doi:10.1080/10408398.2021.1918628.

Joint United Nations Programme on HIV/AIDS (UNAIDS). UNAIDS Data 2018. Geneva: UNAIDS; 2018.

Juma K, Reid M, Roy M et al. 2018. From HIV prevention to non-communicable disease health promotion efforts in sub-Saharan Africa: a narrative review. AIDS 32: S63–73.

Kagaruki GB, Mayige MT, Ngadaya ES, Kimaro GD, Kalinga AK, Kilale AM, et al. Magnitude and risk factors of noncommunicable diseases among people living with HIV in Tanzania: a cross sectional study from Mbeya and Dar es Salaam regions. BMC Public Health 2014; 14:904.

Kansiime S, Mwesigire D, Mugerwa H, (2019). Prevalence of non-communicable diseases among HIV positive patients on antiretroviral therapy at joint clinical research center, Lubowa, Uganda. PLoS ONE 14(8):e0221022

Kingsley LA, Cuervo-Rojas J, Munoz A, Palella FJ, Post W, Witt MD, et al. Subclinical coronary atherosclerosis, HIV infection and antiretroviral therapy: Multicenter AIDS Cohort Study. AIDS 2008; 22:1589–1599.

Krishnan S, Schouten JT, Atkinson B, Brown TT, Wohl DA, McComsey GA, et al. Changes in metabolic syndrome status after initiation of antiretroviral therapy. J Acquir Immune Defic Syndr. 2015;68(1):73–80.

Leung, C., Aris, E., Mhalu, A. et al. Preparedness of HIV care and treatment clinics for the management of concomitant non–communicable diseases: a cross–sectional survey. BMC Public Health 16, 1002 (2016) doi:10.1186/s12889-016-3661.

Magodoro IM, Esterhuizen TM, Chivese T. A cross-sectional, facility based study of comorbid non-communicable diseases among adults living with HIV infection in Zimbabwe. BMC Res Notes. 2016;9:379.

Mathebula et al. The prevalence of selected noncommunicable disease risk factors among HIV patients on anti-retroviral therapy in Bushbuckridge sub-district, Mpumalanga province BMC Public Health (2020) 20:247 https://doi.org/10.1186/s12889-019-8134-x

Matthew Hing, Risa M Hoffman, Juliet Seleman, Florence Chibwana, Daniel Kahn and Corrina Moucheraud (2019). 'Blood pressure can kill you tomorrow, but HIV gives you time': illness perceptions and treatment experiences among

Malawian individuals living with HIV and hypertension. Health Policy and Planning, 34, 2019, ii36–ii44 doi: 10.1093/heapol/czz112

Michelle McMacken and Sapana Shah. A plant-based diet for the prevention and treatment of type 2 diabetes

Ministry of Health . *Kenya national strategy for the prevention and control of non-communicable diseases 2015 - 2020*. Nairobi: Ministry of Health, 2015. [Google Scholar]

Ministry of Health . *Kenya stepwise survey for non-communicable diseases risk factors 2015 report*. Nairobi: Ministry of Health, 2015. [Google Scholar]

Muhammad S, Sani MU, Okeahialam BN. Cardiovascular disease risk factors among HIV-infected Nigerians receiving highly active antiretroviral therapy. Nigerian medical journal: journal of the Nigeria Medical Association. 2013; 54(3):185.

National AIDS and STI Control Programme (NASCOP), Preliminary KENPHIA 2018 Report. Nairobi: NASCOP; 2020.

Nsagha DS, Assob JCN, Njunda AL, Tanue EA, Kibu OD, Ayima CW, Ngowe MN. Risk factors of cardiovascular diseases in HIV/AIDS patients on HAART. The open AIDS journal. 2015;9(51):51–9.

Rooyen JM, Fourie CMT, Steyn HS, Koekemoer G, Huisman HW, Schutte R, Malan L, Glyn M, Smith W, Mels C, Schutte AE. Cardiometabolic markers to identify cardiovascular disease risk in HIV infected black South Africans. S Afr Med J. 2014;104(3):195–9

Patel P, Hanson DL, Sullivan PS, Novak RM, Moorman AC, Tong TC, et al., Adult and Adolescent Spectrum of Disease Project and HIV Outpatient Study Investigators. Incidence of types of cancer among HIV-infected persons compared with the general population in the United States, 1992-2003. Ann Intern Med 2008; 148:728–736.

Rabkin M, Melaku Z, Bruce K, Reja A, Koler A, Tadesse Y, et al. Strengthening Health Systems for Chronic Care: Leveraging HIV Programs to Support

Diabetes Services in Ethiopia and Swaziland. J Trop Med. 2012 ed. 2012; 2012:137460–6. 24.

Romanos-Nanclares A, Willett WC, Rosner BA, Collins LC, Hu FB, Toledo E et al. Healthful and unhealthful plant-based diets and risk of breast cancer in US women: results from the Nurses' Health Studies. Cancer Epidemiol Biomarkers Prev. 2021 Jul 21. doi:10.1158/1055-9965.EPI-21-0352.

Rosenstock IM, Strecher VJ, Becker MH. 1994. The Health Belief Model and HIV Risk Behavior Change. Preventing AIDS. New York: Plenum Press, 5–24.

Sabin CA, Worm SW. Conventional cardiovascular risk factors in HIV infection: how conventional are they? Curr Opin HIV AIDS 2008; 3:214–219. [PubMed: 19372969]

Sanjay B et al. (Stanford Univ., USA). World Cancer Research Fund International, 2014.

Satija A, Hu FB. Plant-based diets and cardiovascular health. Trends Cardiovasc Med. 2018;28(7):437–41. doi:10.1016/j.tcm.2018.02.004.

Schouten J, Wit FW, Stolte IG, Kootstra NA, van der Valk M, Geerlings SE, Prins M, Reiss P. Cross-sectional comparison of the prevalence of age-associated comorbidities and their risk factors between HIV-infected and uninfected individuals: the AGEhIV cohort study. Clin Infect Dis. 2014;59(12):1787–97.

Shah K, Alio AP, Hall WJ, Luque AE. The physiological effects of obesity in HIV-infected patient. Journal of AIDS and Clinical Research. 2012;3(4).

Tesfaye DY, Kinde S, Medhin G, Megerssa YC, Tadewos A, Tadesse E, Shimelis T. Burden of metabolic syndrome among HIV-infected patients in Southern Ethiopia. Diabetes Metab Syndr 2014; 8:102–107.

Treece E.W., Treece J.W. Elements of Research in Nursing, Mosby, St-Louis, 1982.

Tsai AC. Reliability and validity of depression assessment among persons with HIV in sub-Saharan Africa: systematic review and meta-analysis. J Acquir Immune Defic Syndr 2014; 66:503–511.

WHO, 2013.World Health Statistics 2013

WHO. Global Health Observatory Data. NCD mortality and morbidity. 2018 [Available from: http://www.who.int/gho/ncd/mortality_morbidity/en/.

World Health Organization. Non communicable diseases country profiles 2014. Geneva, Switzerland: Wold Health Organization; 2014. [Google Scholar]

Zungu NP, Mabaso ML, KumaloF, Sigida, Mlangeni L, Wabiri N, et al. (2019). Prevalence of non-communicable diseases and associated factors among HIV positive educators: Findings from the 2015/6 survey of Health of Educators in Public Schools in South Africa. PLoS ONE 14(2): e0209756.

APPENDICES

APPENDIX I: LETTER OF INTRODUCTION AND CONSENT

Dear respondents,

My name is Ruth W. Akelola, a PhD student at Masinde Muliro University of Science and Technology. I am undertaking a study on the effect of food-based nutrition intervention on the management of Non-Communicable Diseases among people living with HIV in Western Kenya. Participation in this study is purely on a voluntary basis and there will be no incentive for taking part in the study. This study is meant to generate data that could influence future policies and programs and therefore the feedback obtained from data collected and analyzed will be shared with the relevant stakeholders.

Your participation will be highly appreciated. Whatever information you provide will be treated with respect and confidentiality and will not be used for other purposes other than the objectives of this study.

Thank you.

Ruth W. Akelola

Telephone: 0722321011

Kindly indicate your willingness to participate in the study by ticking on either of the responses.

Respondents consent: (Yes) (No)

APPENDIX II : PARTICPATION CONSENT FORM

I have accepted that I will take part in this study. I have read the information in the introducing letter and had a chance to ask questions which were answered to my satisfaction. I hereby give consent of my participation in the study.

Signature

Date

APPENDIX III: STRUCTURED QUESTIONNAIRE

The questionnaire themes include: socio-demographics, tobacco use, alcohol consumption, diet, physical activity, anthropometric measurements measurements, nutrition and health screening, lifestyle advice, family history, NCDs screening and dietary salt intake. The questionnaire will be interviewer administered. The participants' responses will be entered directly into a paper based instrument. The field supervisor will routinely review the completed questionnaire for completion. The questionnaire will be offered in English and Kiswahili.

Note: The questionnaire should be administered to the adult client and where appropriate the health worker should assist.

Client unique No. _____/ _____/ _____ /
Questionnaire No._____
Name of Interviewer_____Date of interview _____
Name of the respondent_____

I. General Information, Demographic and Socio-economic Characteristics of study participants

1. Health Facility (CCC) Name:_____(Code ____)
   County _____
   Sub-County_____Sub location_____

2. Client characteristics

S.No	Name	Relation to hh head	Sex	Age	Marital status	Religion	Level of educ.	Occupation		Cash Income (Tick)
								O.S	T.W	

CODES

Relationship	**Sex**	**Marital status**	**Religion**
1 Household head 2. Spouse /Wife 3. Sons 4. Daughter 5. Brother/Sister 6. Other relatives 7. Non-relatives	1. Male 2. Female	1. Single 2. Married 3. Separated 4. Widowed	1. Catholic 2. Protestant 3. Adventists 4. Muslim 5. Traditionalist 6. No religion 7. Others (specify
Highest level of Education 1. 99 Preschool 2. Not attended school 3. Lower primary 1-4 4. Upper primary 5-8 5. Secondary 6. College 7. University Not applicable	**Occupational status (O.S)** 1. Unemployed 2. Temporary employed 3. Permanent employed 4. Not applicable	**Type of work (TW)** 1. Farming 2. Herding 3. Artisan / Jua kali 4. Casual labourer 5. Teacher 6. Business 7. Other (specify) 8. N/A	

II. Hellen Keller Food Frequency Question (Modified)

Name of food items (Type of food)	**HOW MANY TIMES DOES HE/SHE EAT THE FOLLOWING? (No. of times)**				
	FOOD CODE	**DAILY**	**WEEKLY**	**MONTHLY**	**NEVER CONSUMED (TICK)**
Staple porridge	01				
Whole milk	02				
Rice	03				
Carrots	04				
Mangoes	05				
Papaya	06				
Eggs	07				
Small fish	08				
Liver	09				
Yellow Sweet Potato	10				
Traditional White Sweet Potato	11				
Cassava	12				
Amaranth	13				
Kunde	14				
Big Fish	15				
Beans	16				
Terere	17				
White Tea	18				
Sukumawiki	19				
Tomatoes	20				

Spinach	21				
Spider weed	22				
Enderema	23				
Avocado	24				
Green bananas	25				
Ground nuts	26				
Soya beans	27				
Maize meal	28				
Kimbo	29				
Cowboy	30				
Chipsy	31				
Malo	32				
Kasuku	33				
Sunflower oil	34				
Chicken	35				
Meat	36				
Cabbage	37				
Green peas	38				
Any other	39				
	40				
	41				
	42				

Questionnaire No._____Client No._____

III. Medical History

Please list any past or current medical conditions that you have or are currently being treated for:

_____

_____

_____

_____

List any medications you are currently taking:

1._____

2._____

3. _____

4. _____

5. _____

Do you take any vitamin/mineral/herbal/food supplements? Y / N (Circle one) If yes, please list:

1._____

2._____

3._____

4._____

5._____

Do you smoke? Y / N (Circle one) If yes, how often/how much:

_____

Do you drink alcohol? Y / N (Circle one) If yes, how often/how much:

_____

IV. Health & Nutrition

1. Do you have a local name for NCDs? 1= Yes 2 =No

If yes, what it is _____

1. – Diabetes_____
2. – Cancer_____
3. – Heart Disease_____
4. –Kidney (Renal Disease)_____
5. – Hypertension_____
6. – Hyperlipidemia_____

2. What is the most common NCD in your community?

1. Diabetes
2. Cancer
3. Heart Disease
4. Kidney(Renal Disease)
5. Hypertension
6. Hyperlipidemia
7. Any other_____

N.B. Please tick the appropriate number(s)

3. Has the client suffered from any of the above mentioned NCDs ? 1=Yes 2 = No

(Request to see the card see the diagnosis and probe further.)

Which one (s)

_____

4. Do you attend clinic of any of the above mentioned NCDs? 1 =Yes 2 = No *(Request to see the card see the diagnosis and probe further.)Which one(s)*

_____

_____

5. Has the client received any supplementation? 1 = Yes 2 = No

Which one _____

When was the last given? _____

6. What type of food products have you received for your condition for the last 3 months? *(Please circle appropriately)*

1. Plumby Nut
2. Nutricet
3. Corn soya Blend
4. Any other. Please indicate

_____

_____

8. How many times a day do you typically eat: _____

9. Do you consume caffeinated beverages on a regular basis? (Check all that apply)
   ____ Coffee ____ Tea ____ Soda ____ Energy Drinks

10. Do you avoid any of the following foods? (Check all that apply)

____ Red meat

____ Fruits

____ Sweets (candy, desserts)

____ Poultry (chicken, turkey)

____ Fried food

____ Alcohol

____ Fish

____ Breads

____ Fats/oils (mayo, dressing, butter)

____ Dairy (milk, cheese)

____ Grains (pasta, rice)

____ Vegetables

____ Fast food

11. Foods you especially like:

_____

12. Foods you especially dislike:

_____

V. Physical Activity History

13. Are you currently physically active? Y / N (Circle one)

If yes, How often: _____ times per week

How long: _____ minutes per session

14. Type of activities:

_____

15. Please rate the average intensity of your workouts: (Circle one)

Light (walking slowly, sitting, standing)

Moderate (walking briskly, heavy cleaning, light bicycling)

Vigorous (hiking, running, fast bicycling, most team sports, weight lifting)

16. What type of exercise do you do?

1. Jogging (>45 mins, <45mins)
2. Walking (>45 mins, <45mins)
3. Any other. Please indicate

_____

_____

17. Do you smoke cigarette?

1. Yes, currently
2. No, stopped smoking
3. No, I have never smoked
4. Do you smoke any other item apart from cigarette? Please indicate

Questionnaire No._____ Client No._____

18. Do you drink alcohol?

1. Yes, currently
2. No, stopped alcohol
3. No, I have never alcohol
4. Do you drink any other type of drink apart from alcohol? Please indicate

---

Questionnaire No._____Client no._____

VI. Food/Dietary intake

Client No._____

Respondent (Mother/Guardian) or Adult client

_____

Does the family _____ (Insert either, always, occasionally or never) have

_____

Please indicate the meals that are usually served in your household?

Meals	Wet season			Dry season		
	Always	**Sometimes**	**Never**	**Always**	**Sometimes**	**Never**
Breakfast						
Lunch						
Supper						
Snacks						

N/B (Tick Appropriately)

Questionnaire No._____ Client no._____

VII: 24-HOUR RECALL QUESTIONNAIRE(modified)

Note: This questionnaire will be done at the health facility , the client will be able to come with the household measures. The limitation will be , that the researcher will not be able to observe the household and the environment.

*Taking measures****: use sufuria, utensils, and the food ingredients used in the household to show the exact amounts, sizes and units used in preparation of the foods or purchased price for unit. Using this, translate the measures into volumes using measuring jugs, or weights using the dietary scales. Requests to see the measures, sizes, foods and ingredients*** ame of the

child/Adult_____ Sex:M /F_____

Date of birth_____

Age_____(months)

Using the 24-hour recall food intake record sheet, fill in the required details in the table:

1. Starting from yesterday morning, what did you feed on?
2. Did you prepare for yourself alone-1, or including other family members-2? _____
3. What did the dish consist of (ingredients)?
4. How much of each ingredient mentioned did you include?
5. What volume was the whole dish after preparation?
6. How much did you eat ?
7. How much was left?

Note: Ask to see and specify measure used under household measure column:

1= teaspoon, 2=tablespoon, 3=cup, 4=bowl, 5=tin, 6=number, 7= unit price, 8=other

24-Hour recall food intake record sheet

Time	Dish	Name of ingredient used for preparation	House hold measure used	Amount in h/h measure	Amount of ingredient in the dish	Volume of complete dish prepared	Amount of food served t	Food consumed	Amount left over

Questionnaire No._____ HH No._____

VIII. Anthropometry

Name of Adult/Child_____ Date of weighing

_____/_____/_____

Age _____ (Months)

Sex of client M/F_____

Sno	Client No.	Name	Sex	Date of birth	Age in years	Weight			Height			MUAC		
						1st	2nd	Av.	1st	2nd	Av.	1st	2nd	Av.

(Take the weight and height of the client.)

All measurements to the nearest 0.5Kg and 0.1cm

APPENDIX IV: MAP SHOWING LOCATION OF AREA OF STUDY

APPENDIX V:NACOSTI

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **626985**

Date of Issue: **12/August/2020**

RESEARCH LICENSE

This is to Certify that Miss.. RUTH AKELOLA of Masinde Muliro University of Science and Technology, has been licensed to conduct research in Bungoma, Busia, Kakamega, Kisumu on the topic: EFFECT OF FOOD BASED NUTRITION INTERVENTION ON MANAGEMENT OF NON COMMUNICABLE DISEASES AMONG PEOPLE LIVING WITH HIV IN WESTERN KENYA for the period ending : 12/August/2021.

License No: **NACOSTI/P/20/6173**

626985

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

APPENDIX VI: INSTITUTIONAL ETHICS REVIEW COMMITTEE

MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY
Tel: 056-31375
Fax: 056-30153
E-mail: ierc@mmust.ac.ke
Website: www.mmust.ac.ke
P. O. Box 190-50100
Kakamega, Kenya

Institutional Ethics Review Committee (IERC)

Ref: MMU/COR: 403012 vol2 (91)

Date: 22nd July, 2020

Ruth Akelola
Masinde Muliro University of Science and Technology
P.O. Box 190-50100
KAKAMEGA

Dear Ms. Akelola

RE: EFFECT OF FOOD BASED NUTRITION INTERVENTION ON MANAGEMENT OF NON-COMMUNICABLE DISEASES AMONG PEOPLE LIVING WITH HIV IN WESTERN KENYA -MMUST/IERC/125/20

Thank you for submitting your proposal entitled as above for initial review. This is to inform you that the committee conducted the initial review and approved (with no further revisions) the above Referenced application for one year.

This approval is valid from **22nd July, 2020 through to 22nd July,2021.** Please note that authorization to conduct this study will automatically expire on **22nd July, 2021.** If you plan to continue with data collection or analysis beyond this date please submit an application for continuing approval to the MMUST IERC by **22nd June, 2021.**

Approval for continuation of the study will be subject to submission and review of an annual report that must reach the MMUST IERC secretariat by **22nd June, 2021.** You are required to submit any amendments to this protocol and any other information pertinent to human participation in this study to MMUST IERC prior to implementation.

Please note that any unanticipated problems or adverse effects/events resulting from the conduct of this study must be reported to **MMUST IERC.** Also note that you are required to seek for research permit from **NACOSTI** prior to the initiation of the study.

Yours faithfully,

Dr. Gordon Nguka (PhD)
CHAIRMAN, INSTITUTIONAL ETHICS REVIEW COMMITTEE

Copy to:
- The Secretary, National Bio-Ethics Committee
- Vice Chancellor

APPENDIX VII:APPROVAL OF PROPOSAL LETTER

MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY (MMUST)

Tel: 056-30870
Fax: 056-30153
E-mail: directordps@mmust.ac.ke
Website: www.mmust.ac.ke

P.O Box 190
Kakamega – 50100
Kenya

Directorate of Postgraduate Studies

Ref: MMU/COR: 509099

Date: 10th June, 2020

Ruth W. Akelola,
HMD/H/01-55294/2017,
P.O. Box 190-50100,
KAKAMEGA.

Dear Ms. Akelola,

RE: APPROVAL OF PROPOSAL

I am pleased to inform you that the Directorate of Postgraduate Studies has considered and approved your Ph.D proposal entitled: ***"Effect of Food Based Nutrition Intervention on Management of Non Communicable Diseases among People Living with HIV in Western Kenya"*** and appointed the following as supervisors:

1. Prof. Edwin Wamukoya - SPHBS&T MMUST
2. Dr. Jane Situma - SPHBS&T MMUST

You are required to submit through your supervisor(s) progress reports every three months to the Director Postgraduate Studies. Such reports should be copied to the following: Chairman, School of Public Health, Biomedical Sciences and Technology Graduate Studies Committee and Chairman, Nutritional Sciences Department. Kindly adhere to research ethics consideration in conducting research.

It is the policy and regulations of the University that you observe a deadline of three years from the date of registration to complete your Ph.D thesis. Do not hesitate to consult this office in case of any problem encountered in the course of your work.

We wish you the best in your research and hope the study will make original contribution to knowledge.

Yours Sincerely,

Prof. Jam Obiri
DIRECTOR, DIRECTORATE OF POSTGRADUATE STUDIES

APPENDIX VIII :RESEARCH APPROVAL BY COUNTY GOVERNMENT OF BUSIA

COUNTY GOVERNMENT OF BUSIA
County Health Director
Health & Sanitation Department
P.O. Box 1040 – 50400
BUSIA, KENYA

CG/BSA/H/ADM/1/56 VOL.II/87

Date: 21st December 2022

The Medical Superintendent
Busia County Referral Hospital

Dear Sir,

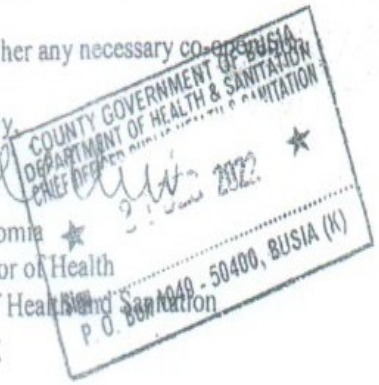
RESEARCH APPROVAL-RUTH WAMATUBA AKELOLA

This is to confirm that the above named who is a PHD student at Masinde Muliro University of Science and Technology (MMUST) has been authorized to conduct a research study entitled "**Effect of food based nutrition intervention on management of non communicable diseases among people living with HIV in Western Kenya**" in Busia County in partial fulfillment of her PHD degree..

The research site is Busia County Referral Hospital CCC. The research has been approved by NACOSTI and MMUST Institutional Ethics Review Commission, both approvals attached for your perusal.

Kindly accord her any necessary co-operation.

Yours faithfully,



Dr. Melsa Lutomia
County Director of Health
Department of Health and Sanitation
Busia County