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Effect of PROLCARMIV on Management of Non-Communicable Diseases Among People Living with HIV in Busia, County Hospital-Kenya

Ruth Wamatuba Akelola*, Wamukoya Edwin, Situma Jane

Department of Nutritional Sciences, Masinde Muliro University of Science and Technology, Kakamega, Kenya

Email address:

megashiftnutrition@gmail.com (Ruth Wamatuba Akelola), rakelola@mmust.ac.ke (Ruth Wamatuba Akelola), ewamukoya@mmust.ac.ke (Wamukoya Edwin), jsituma@mmust.ac.ke (Situma Jane)

*Corresponding author

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Abstract: Good Nutrition optimizes benefits of ART and increases treatment adherence, both prolong 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.

Keywords: Food-Based Nutrition Intervention, HIV, NCDs, PLHIV, PROLCARMIV, Power Porridge

1. Introduction

Non-communicable diseases (NCDs) are responsible for the mortality of around 41 million individuals annually, accounting for approximately 74% of the total global deaths. Annually, a staggering number of 17 million individuals succumb to non-communicable diseases (NCDs) prior to reaching the age of 70. It is noteworthy that a significant majority, amounting to 86%, of these untimely fatalities transpire within nations categorized as low- and middle-income economies. The World Health Organization (WHO) in 2022 [1-4, 18].

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) and 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. In individuals living with HIV (PLHIV), inadequate nutrition accelerates the progression of the disease, heightens the incidence of illness, and reduces overall survival duration. The study conducted by Fathima et al. in 2022 is referenced [5].

The energy requirements of people living with HIV (PLHIV) have been documented to grow, as indicated by NASCOP, 2014 [6]. Consequently, it is necessary to adopt a balanced and diverse dietary approach. Moreover, research has indicated a rise in the prevalence of non-communicable diseases (NCDs) among individuals living with HIV (PLHIV) in comparison to those without HIV. This trend carries significant ramifications for the provision of management, support, and clinical treatment. The study conducted by Mathebula et al. in 2020 [7]. This issue is apparent, particularly in emerging nations where there is a growing prominence of dietary and lifestyle risk factors linked to non-communicable diseases (NCDs). The study conducted by Chhoun et al. in 2017 is referenced as [8]. Both HIV and NCD are medical illnesses that require effective management through a comprehensive approach that encompasses Food, Nutrition, and Dietetics. This study highlights the importance of utilizing locally accessible food resources, doing laboratory and clinical monitoring, promoting behavioral modifications, and providing adherence support in the management of these conditions.

Nevertheless, the present study aimed to extend its scope by implementing an intervention that specifically addresses non-communicable diseases (NCDs) among people living with HIV (PLHIV). This intervention takes a unique approach by utilizing a food-based nutrition intervention, marking the first instance of its implementation within Kenya for this particular population.

2. Methods and Materials

2.1. Study Area and Population

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. Study subjects were People Living with HIV (PLHIV) with NCDs, aged 18 years and above. The County has an approximate area of 1261 square kilometers; this includes 137 square kilometers squares, (which is also under permanent water surface).

2.2. Sample Size Determination by - G Power*

G*Power is a software used to calculate statistical power. The program offers the ability to calculate power for a wide variety of statistical tests including t-tests, F-tests, and chi-square-tests, among others. Additionally, the user must determine which of the many contexts this test is being used, such as a one-way ANOVA versus a multi-way ANOVA. In order to calculate power, the user must know four of five variables: either number of groups, number of observations, effect size, significance level (α), or power (1-β). G*Power has a built-in tool for determining effect size if it cannot be estimated from prior literature or is not easily 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: Non-centrality 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.

Sampling

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

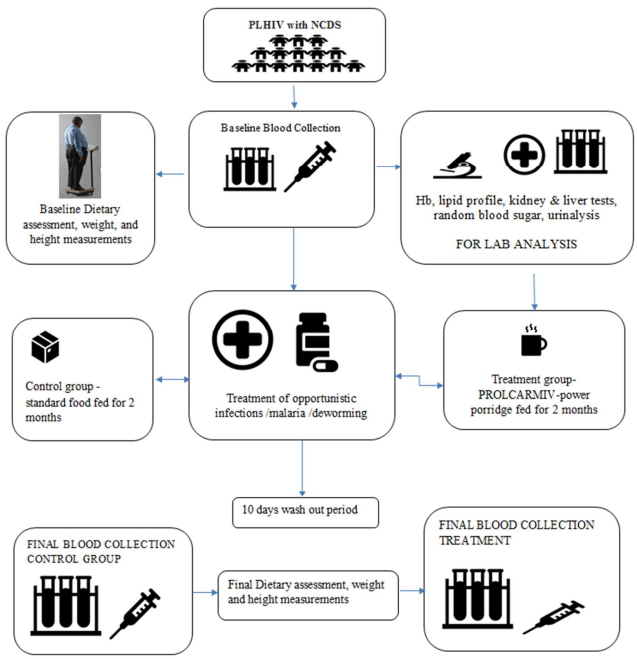


Figure 1. *A Schematic diagram of research design.*

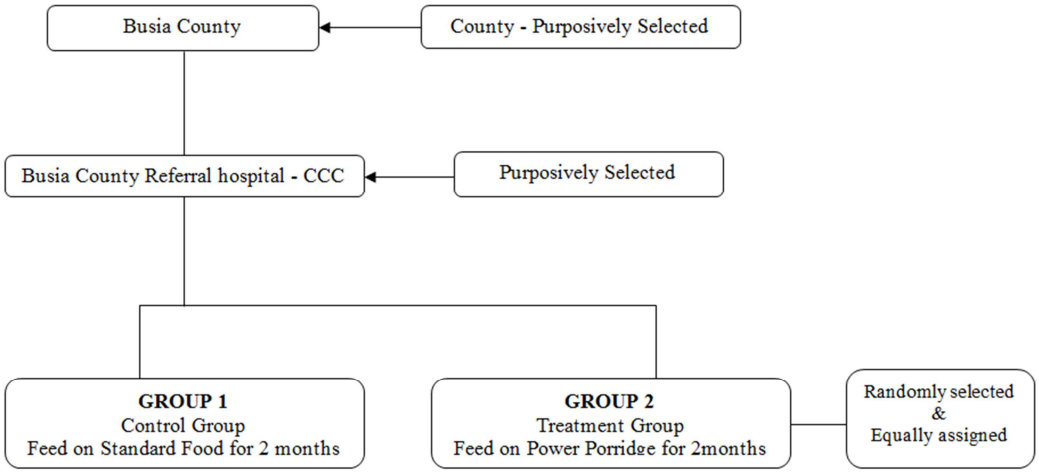


Figure 2. *Summary of the Sampling Procedure.*

2.3. 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 the 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 the 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.

2.4. Study Population

Subjects were PLHIV with NCDs, aged 18 years and above, they were purposefully selected from Busia County referral hospital CCC and randomly placed in two groups.

County's HIV prevalence is 10th highest nationally; it is 1.1 times higher than the national prevalence at 6.7%., County contributed 1.4% and 2.0% of the total new HIV infections in Kenya among children and adults respectively (Busia County Partners report, 2018).

2.5. Measurable Variables

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.

2.6. Quality Assurance

The training was done in one day. During the training the following was stressed, portioning of feeds, the importance of the study and objectives and sticking to the procedure, the 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 the preparation of the porridge. The cooks were supervised.

Figure 3. *Pumpkin chips being dried in readiness for grinding them into flour.*

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 1 Sachet - Plumby 'Nut = 92 gms 1 sachet per person per day	Pumpkin flour = 300gms Soya bean Flour= 385 gms Millet flour = 300gms Sugar = 900gms Sun flower oil = 25 mls Water 19 liters I cup = 500mls per person per day of porridge

2.7. 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.

2.8. Monitoring for Compliance and Quality Control

Monitors gave clients mugs of porridge once they were sitted. In between the feeds other activities were implemented like dietary counseling and training for income generation among others.

Nutritionists at the CCC supervised feeding, kept records for morbidity and the reasons for non-compliance. The feeds were given 5 days in a week excluding, Saturdays, Sundays and holidays. Compliance was defined as 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.

2.9. Logistical and Ethical Considerations

The ethical approval was obtained from Masinde Muliro University of Science and Technology Institutional Ethical Review Committee (IERC); Directorate of Postgraduate; Ministry of Health from the Chief Health officer of Busia County referral hospital; clearance and permit were issued by the National Council for Science and Technology Institute.

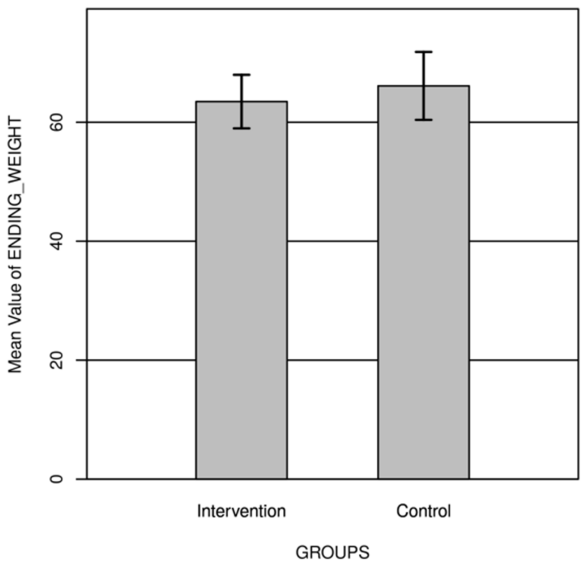
Table 2. *Data Analysis and presentation.*

Data collected at the CCC Objectives 1- 5	Method of Analysis
To establish the prevalence of NCDs among PLHIV	Percentages, Mean, Chi-square, P- values
To determine anthropometric measurements among PLHIV with NCD	Frequencies, percentages, crude odds ratio, Adjusted Odds ratio, P -values, Confidence Interval, mean, SD, t-test
To assess dietary practices among PLHIV with NCD	Frequencies, percentages, crude odds ratio, Adjusted Odds ratio, P -values, Confidence Interval, mean, SD, t-test
To establish a baseline lipid profile, random blood sugar level, hemoglobin level, liver and kidney function of PLHIV with NCDs	Frequencies, Percentages, Mean, SD, Correlation, t-test
To determine the effect of use of standard food product and treatment food product among PLHIV with NCDs	Descriptive statistics Analysis of Variance, t-test

3. Results

Food Consumption Score (FCS) WFP/FAO, 2008 [9] is a proxy for household food security and is designed to reflect the quality of the 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. See Table 2.

To establish the prevalence of NCDs among PLHIV at the CCC in Busia County referral hospital, Kenya. The study findings indicate that a high percentage of the respondents were females as compared to males. The highest percentage study population was women, and most of them were living with HIV and NCDs. See Table 1. 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 [10, 17].



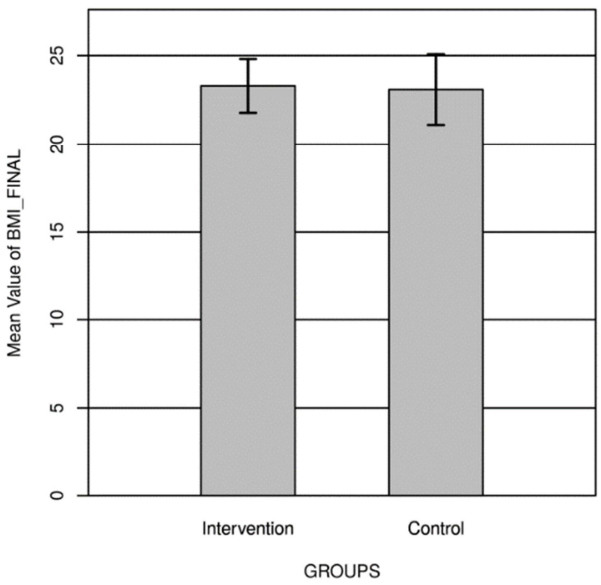


Figure 4. *Ending Weight and final BMI for intervention and control groups.*

What we eat and our nutritional status can affect cardiovascular diseases, some types of cancer, and diabetes, even hypertension. Foods, diet, and nutritional status, including overweight and obesity, are associated with elevated blood pressure, blood cholesterol, and resistance to the action of insulin. These conditions are not only risk factors for NCDs but major causes of illness themselves Sanjay *et al.* 2014. [11, 17, 25] Consuming predominantly plant-based diets reduces the risk of developing obesity, diabetes, cardiovascular diseases, and some forms of cancer. Plant-based diets are high in vegetables and fruits, whole grains, pulses, nuts, and seeds, and have only modest amounts of meat and dairy. These diets help to achieve and maintain a healthy weight, reduce blood pressure, and are also rich in sources of dietary fiber, which protects against colorectal cancer World Cancer Research Fund International, 2014 [12]. This study looked at the effect of a food-based nutrition intervention that was basically plant-based, it focused on soya, millet, pumpkin, and plumpy- 'nut, and the effect on the study variables such as Low-Density Lipid, Total Cholesterol, and Triglyceride was decreased right from baseline to post–interventional.

To determine anthropometric measurements of PLHIV with NCDs at the CCC in Busia County referral hospital, Kenya.

The increase in 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 this cohort there is an effect of the power porridge on the subject's weight.

To assess dietary practices for PLHIV with NCDs at the CCC in Busia County Referral Hospital, Kenya. See Table 2.

In this study, the food consumption score was arrived at by using a modified Hellen Keller's food frequency questionnaire. The food consumption score classifies households into three categories namely; Poor (<21), Borderline (21.5-35), and Acceptable (>35). WFP/FAO, 2008 [13]. 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. 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.

To establish baseline lipid profile, random blood sugar levels, hemoglobin levels, and liver and kidney function of PLHIV with NCDs at the CCC in Busia County referral hospital, Kenya. See table 8.

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.

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).

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. See table 8.

These findings indicate that the treatment food product which was plant-based provided to the intervention group may have had a positive effect 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 [12] 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 [14].

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 [15].

Table 3. *Socio-demographic characteristics.*

Relation to the household 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)
	Not applicable	2 (4.4)
Occupational status	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 4. *Baseline food consumption scores for control and intervention groups.*

Food consumption score (FCS)	**Control**	**Intervention**	**COR (95% CI)**	**AOR (95% CI)**	***P***
	n =23	**n =22**			
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. The *P*-value represents the statistical significance.

Table 5. *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), the p-value is set at 0.05

Table 6. *Baseline Health & Nutrition.*

		N (%)
Do you have a local name for NCDs if yes, what is	No	39 (86.7)
	Yes	6 (13.3)
What is the most common NCDs in your community	Diabetes	7 (15.6)
	Hypertension	34 (75.6)
	Malaria	4 (8.9)

		N (%)
Have you suffered from any of the above-mentioned NCDs, which one	Arthritis	2 (4.4)
	Congenital hearing loss	2 (4.4)
	Heart disease	4 (8.9)
	Hypertension	32 (71.1)
Do you attend the clinic of any of the above-mentioned NCDs, which ones	No	5 (11.1)
	No	25 (55.6)
	Yes	20 (44.4)
Have you received any supplementation	No	41 (91.1)
	Yes	4 (8.9)
What type of food products have you received for your condition for the last 3 months	None	45 (100.0)
How many times a day do you typically eat	1	1 (2.2)
	2	2 (4.4)
	3	42 (93.3)
Do you consume caffeinated beverages on a regular basis	Coffee, tea, soda, energy drinks	2 (4.4)
	Tea	43 (95.6)
Do you avoid any of the following foods	Alcohol, fats oils	16 (35.6
	Breads	2 (4.4)
	Fish	3 (6.7)
	Fruits	3 (6.7)
	Red meat	5 (11.1)
	Sweets	16 (35.6)
Foods you especially like	Amaranth white tea	2 (4.4)
	Fish	2 (4.4
	Grains, fruits and Kienyeji	12 (26.7)
	Spider plant, amaranth, pumpkin leaves	3 (6.7)
	Ugali amaranth, fruits, bananas	2 (4.4)
	Ugali vegetable	11 (24.4)
	Vegetables	10 (22.2)
	White meat	3 (6.7)
Foods you especially dislike	Alcohol	7 (15.6)
	Alcohol and Kunde	4 (8.9)
	Alcohol, fast food	4 (8.9)
	Fast food	5 (11.1)
	Fish	3 (6.7)
	N/a	9 (20.0)
	Pork, alcohol	2 (4.4)
	Pork, bread	2 (4.4)
	Red meat and alcohol	9 (20.0)

Note: Data are presented as n= number of participants, percentage diseases suffered, and food intake

The above study subjects were asked about their knowledge and experience of Non-Communicable Diseases (NCDs).

Table 7. *Medical History.*

Medical history		**N (%)**
Please list any past or current medical condition that has or is 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

The medical history data provided a crucial backdrop against which was used to interpret the effect of the standard

and treatment of food products on the health of PLHIV with NCDs in this population.

Table 8. *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 a 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

A considerable majority of study subjects reported being physically active (71.1%, n=32), while 28.9% (n=13) were not.

Laboratory Analysis

Table 9. *Two-tailed Paired Samples t-test for the Difference Between Baseline HB and post-intervention HB in the 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

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 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 led to a significant change in Hb levels within the intervention group from baseline to post-intervention.

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 10. *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 above 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.

The t-test results provide valuable insights into the changes observed in laboratory chemistry test results between baseline and post-intervention for different groups.

4. Discussion

The concepts of the 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 was required for their improved quality of life.

4.1. 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 agree 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 [14]. 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 [15]. 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 [6]. Lietzman et al recommends 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 [12].

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 et al., 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 [25].

4.2. 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, and 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 [14]. Also, Michelle M et al,.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. This current study is unique because of the use of PLHIV with NCDs; the design selection also is different from Michelle et al 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 previous studies [8, 12, 16].

4.3. 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) [9]. 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.

4.4. 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).

4.5. 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.

4.6. 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.

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.

4.7. 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.

Medical History for control and Experimental groups at baseline

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

4.8. 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.

4.9. 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 [19, 22].

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) [20].

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. Eugenin *et al* 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 [19].

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 [24]. 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 [25].

5. Conclusion

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. Further, findings showed that the average BMI for the intervention group increased; The study established that at baseline lipid profile, hemoglobin levels, and liver and kidney function were similar at baseline and not significant in both the control and experimental group, however post-intervention results on the same 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, indicating some hyperglycemia in subjects both control and experimental, further analysis is recommended to isolate whether the ARVS had caused this impact or it was from the food intervention.

The dietary practices were such that staple porridge, maize meal, and vegetables were consumed on a daily basis which is not in line with the recommendations of the national guidelines on Healthy diets and lifestyles MOH, 2017 [16, 23]. The food consumption score for the study population showed a score of borderline, suggesting that there was a degree of unstable food consumption patterns, indicating household food insecurity and poor quality of diet in this study population. A notable category of poor food consumption score indicates that some households had inadequate access to a diverse and balanced diet, which without intervention may contribute to poor nutritional outcomes.

The compliance rates for the intervention group were good and consistency in attendance was observed as shown in the results, making the food-based intervention key in contributing to the quality of life (QoL) of the study subjects,

increased uptake of services, and adherence to ART for PLHIV with NCDs attending a clinic at the CCC. The collaboration between the Ministries of Health and Public Health and the Ministry of Agriculture and Livestock in the promotion of locally available foods for use will go a long way in sustaining the gains that this study has brought about for PLHIV with NCDs who participated in the study at the Busia County referral CCC. A multi-sectoral approach to support, care, and treatment of PLHIV cannot be over-emphasized. This study has shown that collaboration of health care providers at the CCC improved the uptake of services. Health and Nutrition education are strong components of the continuum of care that is supposed to be provided alongside all other services at the CCC. The study used locally available pumpkin, millet, and soya bean flours as ingredients of the power porridge (PROLCARMIV). 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 their nutrition status.

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ORCID ID

Ruth Wamatuba Akelola: https://orcid.org/0000-0003-4240-2190.

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