EFFECT OF COVI SOUP ON BMI, IMMUNOLOGICAL AND HEMATOLOGICAL PARAMETERS AMONG PEOPLE LIVING WITH HIV IN KAKAMEGA COUNTY, KENYA

Antonette Nanjala Kivelenge

A Thesis submitted to the School of Public Health Biomedical Science and Technology in partial fulfilment for the requirements of the award of Degree of Masters of Science in Medical Dietetics of Masinde Muliro University of Science and Technology

NOVEMBER, 2023

DECLARATION

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

Signature……..... Date……..…...

Antonette Nanjala Kivelenge

HMD/G/01-53689/2019

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance of Masinde Muliro University of Science and Technology a thesis entitled; ***Effect of Covi soup on BMI, Immunological and Hematological Parameters among People Living with HIV in Kakamega County, Kenya***

Signature..... Date.....

Dr Jane Situma, PhD

Senior Lecturer,

Department of Nutritional Sciences

Masinde Muliro University of Science and Technology

Signature..... Date.....

Dr Lucy Mutuli, PhD

Lecturer,

Department of Nutritional Sciences

Masinde Muliro University of Science and Technology

COPYRIGHT

DEDICATION

To my sister, Winnie Kivelenge, who has stood by my side through thick and thin and offered her unlimited support from the start to completion of my studies.

ACKNOWLEDGEMENTS

Thanks to God for bounties of blessings in health, finances and opportune to pursue to completion this course. Regards to my family at large for their love and care that has nourished my journey in studies. Gratitude to Dr Jane Situma and Dr Lucy Mutuli for tender counsel towards achievement of this great milestone. A lot of gratitude to the research assistant, Mr. Caleb Sagam for his expertise. I wish to also recognize my course mates: Emily, Miriam, Mary, Ruth and Sofie. To all of you, Thank you.

I wish to acknowledge the Covi soup research team, Nutritional Sciences department, School of Public Health and Biomedical Technology, the Directorate of Research and Postgraduate and University Research Fund for the physical and financial inputs given that allowed feasibility of this study.

ABSTRACT

Globally, 37 million people living with HIV (PLWH) are susceptible to severe acute respiratory syndrome Corona Virus 2 (SARS-CoV-2) infection that causes Coronavirus Disease 2019 (COVID 19). The pandemic can potentiate adverse health outcomes for PLWH. Lack of an antiretroviral treatment (ART) for this acute infection halts the fight against COVID 19 threatening PLWH lives. Supportive therapy contributes in the fight against this pandemic. The main objective was to determine effect of Covi soup on BMI, immunological and hematological parameters among PLWH. Specific objectives were: to determine effect of Covi soup on; Body Mass Index (BMI); CD4+ cell count; Viral Load (VL) and hematological parameters. This was an Open Randomized Control Trial (RCT) conducted in Kakamega County Teaching and Referral Hospital (KCTRH) Comprehensive Care Centre (CCC). Purposive sampling was used to select the study area and study site while systematic random sampling was used to select the study participants. Block randomization using sequentially numbered opaque envelopes was used to place participants in either treatment group or control group. Approximately 48,752 are PLWH in Kakamega County from which a sample of 60 was selected for the study. A RCT formula was used to calculate a sample size of 30 for treatment and control group. Treatment group received standard care and Covi soup while the control group exclusively received standard care. Data was collected using researcher administered questionnaire and laboratory report forms. Data was keyed in statistical packages for social sciences (SPSS) and analysed using paired t-test to determine effect of Covi soup on BMI, CD4+ cell count, VL and hematological parameters. A total of 21(70%) participants in the control group and 20 (67%) in the treatment group were included in data analysis. The study findings showed no significant effect of Covi soup on the CD4+ cell count (p=0.838) and Hb (p=0.116) in the control group. There was a significant effect of Covi soup on CD4+ cell count (p=0.012) and Hb (p=0.010) in the treatment group. No significant effect was observed in the BMI (p=0.092, p=0.149), VL (p=0.051, p=0.298), MCV (p=0.635, p=0.122), MCH (p=0.870, p=0.352) and MCHC (p=0.800, p=0.528) in both the control group and treatment group respectively. The study concluded that Covi soup had an effect on the CD4+ cell count and Hb of PLWH in KCTRH. The findings of this study can be used by PLWH to prevent SARS-Cov-2 infection and reduce the severity of COVID 19.

TABLE OF CONTENTS

LIST OF TABLES

.

LIST OF FIGURES

LIST OF APPENDICES

LIST OF ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immunodeficiency syndrome
ART	Antiretroviral treatment
BL	Baseline
BMI	Body Mass Index
CDC	Center for Disease Control
Cms	Centimeters
CCC	Comprehensive Care Centre
COVID 19	Coronavirus Disease 2019
CMV	Cytomegalovirus
DM	Diabetes mellitus
EPLWHA	Elderly people living with HIV/AIDS
FDA	Food Drug Administration
Hb	Haemoglobin
HCV	Hepatitis C Virus
HSV	Herpes simplex virus
HDL	High Density Lipoproteins
HAART	Highly Active Antiretroviral Treatment
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
IgE	Immunoglobulin E
INRs	Immunological Non-Responders
IREC	Institutional Research Ethics Committee

KCTRH	Kakamega County Teaching and Referral Hospital
Kgs	Kilograms
LTR	Long terminal repeat
LDL	Low Density Lipoproteins
MMUST	Masinde Muliro University of Science and Technology
MCH	Mean Corpuscular Haemoglobin
MCHC	Mean Corpuscular Haemoglobin Content
MCV	Mean Corpuscular Volume
m^2	Meters square
NACOSTI	National Commission for Science, Technology and Innovation
NK	Natural Killer
NCD	Non-communicable diseases
OIs	Opportunistic Infections
PLWH	People Living with HIV
PS	Post Study
RBC	Red blood cell
SARS-CoV-2	Severe Acute Respiratory Syndrome Corona Virus 2
SPSS	Statistical Packages for Social Sciences
TB	Tuberculosis
VL	Viral Load
WHA	World Health Assembly
WHO	World Health Organization

OPERATIONAL DEFINITION OF KEY TERMS

Covi soup	A formulation made from mixing seven ingredients; Butternut squash, ginger, garlic, chia seeds, sunflower seeds, chili pepper and turmeric.
Haematological parameters	Hb, MCV, MCH and MCHC
Immunological parameters	CD4+ cell count and VL
Nutrition status	BMI
Standard care	Nutritional counselling as per the Kenya National Guidelines on Nutrition in HIV/AIDs and Anti-HIV drugs adherence.
Treatment	Administration of Covi soup

CHAPTER ONE

INTRODUCTION

1.1 Background information of the study

The global burden of HIV/AIDS is approximately 37 million (Govender et al., 2021). The treatment target is at 75-79-81 similar to 48% viral suppression (Pandey & Galvani, 2019). Over half of the 37 million PLWH are female (Challacombe, 2020). Sub-Saharan Africa is highly burdened; with 75% of deaths, 65% of new infections and where we have 71% of PLWH resided (Dwyer-Lindgren et al., 2019). Eastern and Southern Africa approximately has 20 million PLWH; Western and Central Africa has approximately 5 million; Middle East-North Africa recording approximately 240,000 PLWH (González-Alcaide et al., 2020).

Globally, Kenya is ranked among the top with regards to PLWH with an incidence of 1500 PLWH in every 100,000 person (Chen et al., 2019). In Kenya, 1.5 million people live with HIV/AIDS (PLWHA) with 1.4 million comprising the adult population (NACC, 2018). The national adult HIV prevalence is close to 5.0% with the rate being higher in women 5.2% (Nyamoita Mokua et al., 2019). There were 53,000 newly HIV infected people in Kenya in 2017 (Kiptinness & Kiwanuka-Tondo, 2019). Despite the high prevalence, there is marked variation in HIV prevalence in Kenya per the counties (Magadi et al., 2021). Nairobi county has 171,510 PLWH and 2,500 HIV related deaths yearly occurrence (Nyagah et al., 2019). Eight counties in Kenya contribute to more than 50% of the PLWH: Nairobi 6.1%, Homa Bay 20.7%, Kisumu 16.3%, Siaya 21.0%, Migori 13.3%, Kiambu 4.0%, Kakamega 4.5% and Mombasa 4.1% (NACC, 2018). Kakamega County has a prevalence of 4.5% of PLWH with the prevalence highest in women 5.6% than men 3.4% (NACC, 2018).

In early 2022, Kenya suffered > 300,000 cases and > 5,000 deaths (Nasimiyu et al., 2022). Globally, 37 million PLWH are susceptible to SARS-CoV-2 (Jiang et al., 2020). There is no treatment for COVID 19 (Feng, n.d. 2020). These halts the fight of COVID 19 threatening PLWH lives (Gad et al., 2021). These immune-compromised populations can easily be infected with COVID 19 (Lancent, 2020). The pandemic's indirect effects such as social anxiety adversely affect the health of PLWH (Ridgway et al., 2020). The suppressed immunity that makes PLWH prone to tuberculosis (TB) also exposes them to COVID 19 (Adepoju, 2020). Adequate CD4 count and undetectable VL has been reported to decrease the likelihood of poor COVID 19 prognosis among PLWH to a level comparable with healthy population (Cooper et al., 2020). This makes it very critical to identify strategies other than ART that will help PLWH to have normal BMI, adequate CD4+ cell count, undetectable VL and adequate hematological parameters to decrease their likelihood of suffering severe forms of COVID 19 disease.

1.2 Problem statement of the study

An effective antiviral treatment for COVID 19 has not been discovered to date (Feng, N.D, 2020) and yet, there are 37 million PLWH globally susceptible to SARS-CoV-2 (Jiang et al., 2020). This impedes strategies put in place to fight COVID 19 threatening PLWH lives (Gad et al., 2021). Sub-Saharan Africa is at risk of increased COVID 19 cases driven by number of PLWH (Danwang et al., 2022). The high prevalence of PLWH in Kakamega County, 4.5% (NACC, 2018), indicates that the county can have COVID 19 cases resulting from PLWH. This burden from both HIV and COVID 19 infections is a syndemic which calls for innovative and local solutions that will ensure wellbeing of the County.

The possibility to halt the HIV epidemic has not been achieved (Teshale & Tesema, 2022) amidst the COVID 19 pandemic which created additional setbacks (Barr et al., 2021). Concentrating more on COVID 19 than HIV in Africa reversed the achievements made in HIV care and treatment continuum (Uwishema et al., 2022). COVID 19 impacted negatively on the HIV care and treatment continuum globally (Rick et al., 2022). The social anxiety among other effects of the pandemic adversely affected the health outcomes of PLWH (Ridgway et al., 2020). PLWH live longer and develop conditions that exacerbate COVID 19 (Folayan et al., 2022). Besides, PLWH are immune-compromised which increases their risk of contracting COVID 19 (Lancent, 2020). HIV depletes CD4 cells consequently decreasing immune ability to fight COVID 19 (Danwang et al., 2022). PLWH are highly susceptible to tuberculosis and COVID 19 as well (Adepoju, 2020). HIV infection is a marker for poor COVID 19 outcomes regardless of the CD4 cell count (Tesoriero et al., 2021), (Parise Adadi & Kanwugu, 2020). Higher rate of coexisting

conditions and side effects of ART increase the risk for COVID 19 related complications (Nagarakanti et al., 2021).

1.3 Objectives of the study

1.3.1 Broad Objective

Study objective was to establish effect of Covi soup on BMI, Immunological and Hematological parameters among people living with HIV in Kakamega County, Kenya

1.3.2 Specific objectives

1. To assess effect of Covi soup on BMI among PLWH in KCTRH.
2. To determine effect of Covi soup on CD4+ Count among PLWH in KCTRH.
3. To establish effect of Covi soup on Viral Load among PLWH in KCTRH.
4. To ascertain effect of Covi soup on hematological parameters among PLWH in KCTRH.

1.4 Research Questions

1. What is the effect of Covi soup on BMI among PLWH in KCTRH?
2. What is the effect of Covi soup on CD4+ Count among PLWH in KCTRH?
3. What is the effect of Covi soup on VL among PLWH in KCTRH?
4. What is the effect of Covi soup on hematological parameters among PLWH in KCTRH?

1.5 Justification of the study

It is very critical to identify strategies other than ART that would give extra deterrents to fight COVID 19 among PLWH in Africa. Kenya with 4.9% (NACC, 2018) prevalence is among the leading countries with PLWH. Kakamega County contributes to this high prevalence at 4.5% (NACC, 2018). The risk of having COVID 19 cases resulting from

PLWH is high in Kakamega and Kenya at large. This study was conducted to determine whether this local innovation; Covi soup, can be used as an extra deterrent to fight COVID 19 among PLWH. Hence reducing the disease burden among the PLWH.

New knowledge has been developed as an innovation which can be transferred to key stakeholders like Ministry of Health to allow adaptation and use for the benefit of the general population and PLWH.

Policy makers and other stakeholders can find study findings useful in policy formulation and implementation.

1.6 Significance of the study

Study findings can be used to contribute attainment of sustainable developmental goal (SDG) number three of good health and wellbeing. The effect of Covi soup on the BMI, immunological and hematological parameters can be scientifically proven and whether this could give extra deterrents to fight COVID 19 among PLWH. The increased possibility of COVID 19 cases resulting from PLWH can be mitigated in Kakamega County and Kenya-Africa at large. Covi soup can be used as a home remedy to promote universal health care in the Bottom-up Economic Transformational Agenda (BETA) of Kenya. This remedy can be assimilated for clinical and community practice in Kenya to fast track the attainment of vision 2030 of a prosperous nation with a high quality of life. The novel findings from this study on the effect of Covi soup on BMI, immunological and hematological parameters among PLWH can add knowledge to the existing literature.

1.7 Scope of the study

Study participants were PLWH attending comprehensive care in KCTRH between 15 to 65 years in Kakamega County. The study parameters were: BMI; CD4+ cell count; VL; Hb; MCV; MCH and MCHC.

1.8 Limitations of the study

Sample size derived from the RCT formula was not large enough for the study results to be inferred to the general population of PLWH. This was contributed with fewer similar studies done previously to give the effect size and SD values needed for calculation of the sample size. This was controlled by using a high dropout rate.

The study design was an open randomized control trial involving treatment group administered standard care alongside Covi soup and control group exclusively administered standard care. Aspects of sharing of information as well as the treatment arose in scenarios where two participants from either the treatment or control group came from the same family. This was controlled by placing participants from the same family in the same study group.

The study relied on the participant ability to take the treatment according to the prescription and there was no way to ascertain whether it was done correctly or not. Strict instructions were given for adherence to the administered intervention. Frequent reminder was made through phone calls and short messages on the importance of adhering to the intervention.

1.9 Delimitations of the study

This study was limited to finding out effect of Covi soup on the BMI, CD4+ count, VL, Hb, MCV, MCH and MCHC. BMI was an important parameter in predicting HIV progression and risk of getting opportunistic infections. CD4+ count and VL formed the

immunological components of the study. CD4 + cells are the major immune cells affected by the HIV leading to deterioration of immunity among PLWH. VL was also an important component in predicting the capacity of the CD4+ cells to fight opportunistic infections and coinfections among PLWH. Other immunological components like the B cells, immunoglobulins, neutrophils, helper T cells and cytotoxic T cells were not tested in this study. This is because they are not significantly affected by the HIV virus hence cannot be used to predict the immune status among PLWH. Hematological parameters included: Hb level, MCV, MCH and MCHC. HIV infection has been associated with iron deficiency anaemia, pernicious and megaloblastic anaemia.

1.10 Theoretical Model

1.10.1 Health Belief Model

The HBM by Hochbaum & Rosenstock, 1952 (**See figure 1.1**) has been extensively used to predict health related behavior and compliance to medical treatments. The HBM has six components Perceived severity which explains a health behavior to avoid a serious consequence; Perceived susceptibility that shows health behavior change if at risk; Perceived benefit that explains behavior change if getting something in return; Perceived barrier that explains the difficulties of behavior change; Cues to action which are factors that facilitate behavior change and Self efficacy which is the ability to make a behavior change. The HBM designs both short and long term interventions (Sutliffe et al., 2019), (Liu et al., 2018). The HBM designs strategies that promote healthy behaviors, however not accounting for habitual behaviors, economic and environmental factors that affect behavior and individual beliefs. HBM was adopted in this study to employ strategies that

would promote adherence to the administered interventions in both control and treatment group.

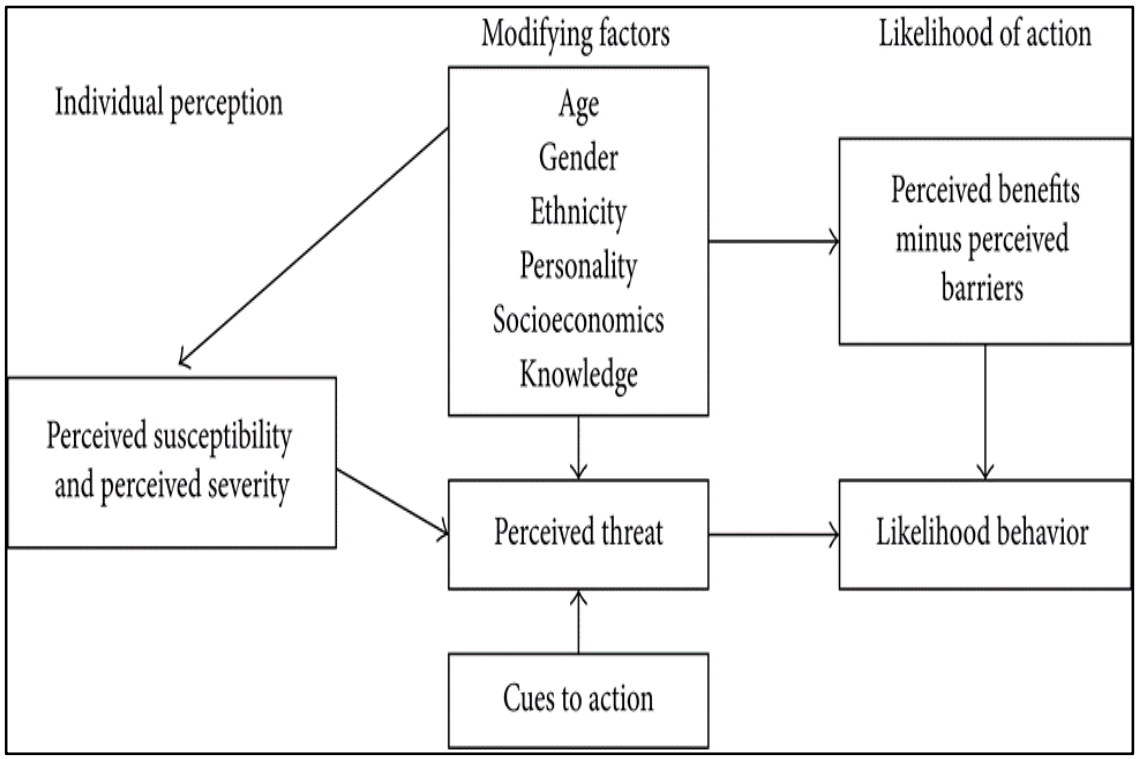


Figure 1. 1:Health belief model by Godfrey Hochbaum, 1952

1.11 Conceptual Framework

Effectiveness of HBM to promote adherence to an intervention was adopted in this study to promote adherence to nutrition counseling guidelines, anti-HIV drugs and use of Covi soup among the study participants. Both groups were subjected to an intense exercise in which the participants were educated on severity and susceptibility of COVID 19 coinfection, benefit of having normal BMI, improved immunological and hematological parameters in the fight against COVID 19, the barriers in using Covi soup such as sharing with family members, cues to action that would promote their health behavior and their self-efficacy to believe in the health behavior that ultimately will affect their likelihood of adherence to the interventions administered.

The independent variable was Covi soup (**See figure 1.2**) whose effect was tested on: BMI (kg/M^2); CD4 + count (cells/µL); VL (copies/mL); Hb (g/dl); MCV (fL); MCH (pg) and MCHC (%) which were the dependent variables. Intermediate variables that could attribute to the effect on the dependent variables were; Age, duration with infection, receipt of support, type of medication, number of household members and dietary habits. In this study, the effect attributed by the intervening variables was held constant by ensuring that both the control group and treatment group had equal distribution of these variables. The outcome was enhanced nutritional, immunological and hematological status among PLWH in Kakamega County following uptake of Covi soup.

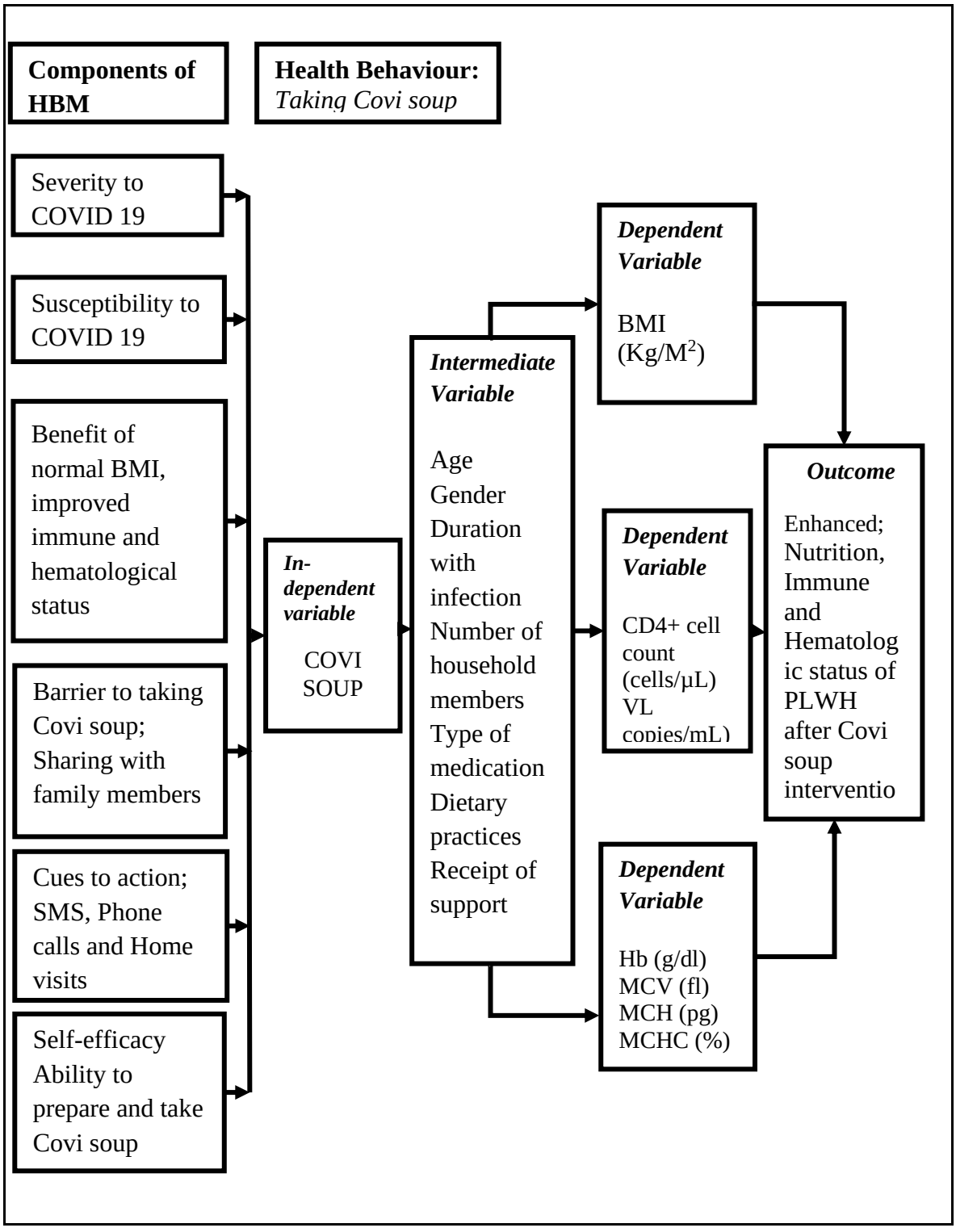


Figure 1. 2: Researcher developed Conceptual Framework 2023

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Chapter two covers prevalence of HIV/AIDs and Covid 19 disease, Synergistic effect of HIV/AIDS and Covid 19 disease, BMI, immunological and hematological changes in HIV/AIDs. Each ingredient of Covi soup is reviewed on how they augment the BMI, immune and hematological parameters.

2.2 Prevalence of HIV/AIDs and Covid 19 Disease

HIV/AIDS global cases stand at 37 million translating to 0.5% of the total world population (Govender et al., 2021). The HIV treatment target has achieved about 50% viral suppression (Pandey & Galvani, 2019). Over half of the population of PLWH are female (Challacombe, 2020). Sub-Saharan Africa is highly burdened with 71% of PLWH (Dwyer-Lindgren et al., 2019). Eastern-Southern Africa records 20 million PLWH, Western-Central Africa approximately 5 million, Middle East-North Africa recording about 250,000 (González-Alcaide et al., 2020). Kenya is listed among countries with highest number of PLWH (Chen et al., 2019). There are about 1.5 million PLWHA in Kenya, of these, about 1.4 million form the adult population. This high prevalence has put Kenya at fourth position with PLWHA globally (Kiptinness & Kiwanuka-Tondo, 2019). The national adult HIV prevalence is about 5.0% with the rate higher among women 5.2% (Nyamoita Mokua et al., 2019). There is marked regional variation in HIV prevalence in Kenya (Magadi et al., 2021). Nairobi has 171,510 PLWH and 2,500 HIV related deaths occurring annually (Nyagah et al., 2019). Eight counties contribute to more than 50% of the PLWH: Nairobi 6.1%, Homa Bay 20.7%, Kisumu 16.3%, Siaya 21.0%, Migori 13.3%, Kiambu 4.0%, Kakamega 4.5% and Mombasa 4.1% (NACC, 2018). In Kakamega County,

women bare the highest burden of HIV infection, 5.6% than men 3.4% (NACC, 2018). In March 2022, approximately 500 million COVID 19 cases and about 6 million mortality of COVID 19 were confirmed globally (WHO, 2022). Over 10 million cases and 200 thousand mortalities occurred in Africa as of 22nd January 2022 (Fulk et al., 2021). The leading countries are South Africa at 57.4%, followed by Ethiopia at 6.0%, Nigeria at 5.0%, Algeria at 4.3% and fifth is Ghana at 4.0% (Adjei et al., 2021). Kenya experienced various phases of the pandemic; Beginning with the virus introduction in the country, emergence of variants of concern (VoCs), restrictions, vaccination and uplifting of most restrictions (Nasimiyu et al., 2022). Over 300,000 COVID 19 cases and 5,000 related mortalities were confirmed by January 2022 in the country (Nasimiyu et al., 2022). An effective antiviral treatment for SARS-CoV-2 has not been found yet (Feng, n.d. 2020). Sub-Saharan Africa is at risk of increased COVID 19 cases resulting from HIV patients (Danwang et al., 2022). Kakamega county is among the counties in Kenya at risk of increased COVID 19 cases given the high number of PLWH.

2.3 Synergistic effect of HIV/AIDs-Covid 19 Disease

HIV/AIDS-COVID 19 diseases vary on their transmission modes with one being a chronic disease while the latter is an acute infection (Edelman et al., 2020). COVID 19 can lead to adverse health outcomes for PLWH through the indirect effects (Ridgway et al., 2020). Comorbidities, lower CD4 count and high viral load increases severity of COVID 19. The complications of COVID 19 are even higher for PLWH with low CD4 cell count and not on ARV regimens (Parise Adadi & Kanwugu, 2020). Coexisting conditions, side effects of ARTs and cardiovascular risk factors increases the risk of COVID 19 complications among PLWH (Nagarakanti et al., 2021). HIV is a marker for adverse COVID 19 among PLWH (Tesoriero et al., 2021). The immunity that makes PLWH susceptible to

tuberculosis also makes them vulnerable to COVID 19 (Adepoju, 2020). Globally, there are 37 million PLWH vulnerable to COVID 19 (Jiang et al., 2020). These immune-compromised populations are at risk of COVID 19 (Lancent, 2020). PLWH greater risk of getting COVID 19 disease associates with vulnerability to even opportunistic pathogens. An effective ART for COVID 19 has not been discovered yet (Feng, n.d. 2020). Lack of effective ART against SARS- COV-2 makes it hard to fight the disease that threatens PLWH lives (Gad et al., 2021). Despite this synergistic effect of the two pandemics, PLWH have not been given extra measures to help them fight COVID 19. The convention strategies put in place to combat COVID 19 among the general population are the same strategies applied to PLWH. This calls for extra deterrents in the fight against COVID 19 among PLWH (Gad et al., 2021).

2.4 Body Mass Index in HIV Infection

High BMI is an emerging problem in PLWH (Khatri et al., 2020). High BMI was found in 21% of HIV patients in Jimma zone hospitals, Ethiopia (Yitbarek et al., 2020). Cases of obesity in PLWH has increased over the years which is a true image of the population at large (Bei, 2017). Obesity has been associated with early clinical stage of HIV and low CD4 count (Sorungbe et al., 2021). HIV infected women are more likely to have increased BMI with abdominal obesity whereas men with HIV infection tend to have a lower BMI (Saito et al., 2020). Central obesity is now more common in PLWH (Florindo & Latorre, 2006), while wasting syndrome is now less observed among PLWH (Tshikuka et al., 2020). Increased BMI causes poor adherence and virological failure (Xu et al., 2021). Overweight and obesity also increase cognitive impairment in PLWH (Jumare et al., 2020). Obesity increases human morbidity and mortality. Adverse consequences of obesity have been reported among PLWH yet we have few obesity treatments in this

population (Germain, 2017). This calls for new insights into human obesity and therapeutics that will resolve this emerging problem among PLWH (Yong Lu et al., 2019). Nutritional interventions need to be strengthened among PLWH (Daka & Ergiba, 2020).

2.5 Immunological Changes in HIV Infection

CD4 cell count and VL are the biochemical parameters used for indicating disease progression and treatment outcomes (Shoko & Chikobvu, 2019). For instance, CD4 + count and VL are considered predictors for Tuberculosis (TB) development (Zerdali et al., 2021). PLWHA with CD4+ cell count 200 - 499 are more likely to experience exhaustion than those whose CD4 count is > 500 count (Gebreyesus et al., 2020). A low CD4 count increases symptoms of HIV (Farhadian et al., 2021). The advanced HIV infection with a decline in CD4 + count to below 200/mm3 causes AIDS (Bhardwaj et al., 2020). This decline increases mortality (Akbari et al., 2019). Target of HIV virus is the vital CD4+ cells (Laila et al., 2019). Even persistent viral suppression, optimal treatment fails to restore CD4+ counts to >1000 cells/mL in Immunological Non-Responders (INRs) (Yang et al., 2020). The failure of the ART to restore the CD4 + count back to the normal ranges among PLWH calls for new mechanisms that can be employed to address this problem. Especially in this era of two pandemics from both HIV/AIDS and COVID 19, PLWH with declining CD4 + count despite management of viral replication with ART, seemingly are at risk of morbidity and mortality.

2.6 Hematological Changes in HIV infection

Anemia is Hb <12.0 g/dL in women and <13.0 g/dL men (Berhane et al., 2020). Globally about 2 billion people suffer from anemia with 1 million annual deaths occurring in Sub-Saharan Africa (SSA) and South-East Asia (Anjulo et al., 2019). Globally, anemia prevalence ranges from 23% to 50% and in Africa from 24% to 58% (Care et al., 2019). This indicates that anemia in PLWH is more common in the third world countries than in the first world countries (Care et al., 2020). Microcytic hypochromic anemia is the most common erythrocyte complications among HIV patients with CD4+ count < 350 cells/uL (Abonyo, Collins, et al., 2020). Anemia severity increases with decline in CD4 count (Gebremedhin & Haye, 2019). It is associated with presence of opportunistic infections (OIs), World Health Organization (WHO) HIV stage III and IV, low Body Mass Index (BMI) and anti-TB treatment (Aynalem et al., 2020). The bone marrow is the central target of the HIV virus, ARVs and effects of opportunistic pathogens (Marchionatti & Parisi, 2021). HIV infection contributes to anemia through red blood cell (RBC) haemolysis and ineffective production in the spleen, neoplastic disease, gastrointestinal lesions accompanying OIs and deficiencies of vitamin B12, folate, or iron (Harding et al., 2020). Zidovudine (AZT) is also associated with hematological toxicity which causes anemia (Getaneh et al., 2021). It has been established that a higher Hb level decreases the risk of death in PLWH receiving ART (Wang et al., 2021). In accordance with the World Health Assembly (WHA) which aims to reduce anemia prevalence in women of reproductive health by 50% between 2012 and 2025 (Williams et al., 2019). To achieve this target among PLWH can be very challenging because of the multifaceted attacks on the bone marrow. Therefore, this calls for strategies that will help to alleviate various forms of

anemia that present among PLWH that resonates from the multiple effects of the HIV virus, ARVs and effects from OIs.

2.7 BMI, Immunological and Hematological Augmenting Foods

2.7.1 Ginger

The properties of ginger that augment immune status have been examined through fish, birds, and human model (Garnier & Shahidi, 2021). Gingerols is the active compound in ginger roots with anti-inflammatory and antioxidant health benefits (Joshua et al., 2021). Other activities of ginger are antibacterial, neuroprotective and anticancer which are attributed to bioactive compounds such as gingerols. For instance, carrot-ginger blend supplementation increases CD4+ counts among PLWH on ART (Joshua et al., 2021a). Ginger essential oil improves immunity in immune suppressed mice (Namdeo, 2021). *Zingiber officinalis* is a common food with proven antivirus activity (Prinsloo et al., 2018), (Wulantresna et al., 2021). The dried rhizomes of ginger affectively work against common cold rhinovirus due to presence of β-sesquiphellandrene (Mahak Divya, Sanghi, Priya, Mishra, Divya, Puri, 2021). In-vitro studies have shown that ginger inhibits proteases of several viruses (Yaseen et al., 2021a). Nutritionally, ginger contains vitamin C, magnesium, manganese, iron, copper, calcium, folate, niacin, choline, zinc, omega-3 and omega-6 (Omoruyi et al., 2021). Ginger is more suitable since it does not affect HAART and is effective in reducing antiretroviral-induced nausea and vomiting (Kyle Burton, 2017). It is also considered as safe by Food Drug Administration (FDA) (Sieniawska et al., 2020).

2.7.2 Garlic

Garlic is scientifically known as *Allium sativum* (Abue et al., 2021). Garlic protein stimulates immune cells (Namdeo, 2021), (Alhazmi et al., 2021). The immunological effect of garlic in mice has been shown in leukocyte and γ globulins activity (Daniela et al., 2020). Organosulfur compounds in garlic; allicin, diallyltrisulfide, and ajoene exhibit antiviral properties (Rahman et al., 2021). Ajoene imparts antiviral action on herpes simplex virus (HSV), cytomegalovirus (CMV) , the flu infections, type 2 rhinovirus and HIV-1 besides strengthening the CD4 T-lymphocytes action (François et al., 2020). Garlic alleviates symptoms and prevents viral re-infections (Yaseen et al., 2021b). Garlic extracts regulate and maintain the immune system homeostasis.

2.7.3 Chilli pepper

Capsaicin provides the necessary benefit for a healthy immune system (Sreshtaa et al., 2021). Capsaicin is an analgesic, immune booster, manages obesity, cardiovascular diseases, gastric ulcers and cancers (Rout & Mohanty, n.d.). The immune-enhancing capabilities of capsaicin include increased spleen lymphocyte proliferation and increased response to induced delayed-type hypersensitivity in mice (Garnier & Shahidi, 2021). Capsaicin is rich in folic acid, copper and iron hence helps with new blood cell formation capable of treating symptoms of anaemia and fatigue. (Madala & Nutakki, 2020). Red chili peppers are rich in β-carotene and green chili contains high amount of vitamin C which strengthen the immune system of the body (Chakrabarty et al., 2017). Capsaicin alleviates symptoms like stuffy nose, sneezing, postnasal drip and congestion (Sharma, 2020). Capsaicin helps the immune system to destroy bacteria (Laurentiu Tatu et al., 2019).

2.7.4 Turmeric

Turmeric is extracted from the rhizomes of *Curcuma longa* (Mahak Divya, Sanghi, Priya, Mishra, Divya, Puri, 2021). Turmeric is a rich sources of Iron which is important for improving immunity (Namdeo, 2021). It boosts the CD4+, CD8+ T cells, Th1 type cytokines, reduces Treg cells and decreases T cell apoptosis (Garnier & Shahidi, 2021). Curcumin shows activity against pathogens including influenza virus, Hepatitis C Virus (HCV), HIV and SARS-CoV-2 (Alhazmi et al., 2021), (Chopra et al., 2021). It inhibits HIV protease and integrase, inflammatory molecules and HIV associated kinases. Curcumin prevents transcription of HIV-1 (Delshadi et al., 2021). Besides, it enhances conventional treatment and minimizes their side effects (Sahdeo Prasad, n.d.).

2.7.5 Chia Seeds

Chia seeds, scientifically known as *Salvia hispanica* (Rubavathi et al., 2020). Chia seeds have omega-3 and omega-6 (Akash et al., 2020). Old weanling male Wister rats fed on chia seed were reported to have higher concentration of Immunoglobulin E (IgE) (Ullah et al., 2016). Another experimental study treating Diabetic rats showed improvement in immunity which was better enforced by chia seeds (Muna Ali, 2020). Chia seeds stimulate humoral immunity of birds (Alkenany et al., 2021). Chia seed help in chronic diseases (Dwivedi et al., 2020). Chia seeds contain complete proteins, fibre, fat and vitamins with antioxidant properties good for immunity (Virginia Melo-Ruíz et al., 2016). Fishy flavour, diarrhoea and gastrointestinal-tract problems are not reported with chia seeds giving it an upper hand for boosting immunity of individual (Dinçoğlu & Yeşildemir, 2019).

2.7.6 Butternut Squash

Cucurbita moschata is also known as Butternut squash (Suradkar et al., 2017). The bioactive polysaccharides in *Cucurbita Moschata* can be developed into a therapeutic agent (Jiwani et al., 2020). Butternut squash contains nutrients used to augment the nutrient needs of consumers preventing chronic diseases and alleviating several micronutrient deficiencies (Linda, 2018). Squash seed protein hydrolysate and skin phenol lower blood glucose using α -amylase and shows antihypertensive capability (Li, 2020). Squash is beneficial to boost immunity, anti-inflammatory, and contains beta-carotene, calcium and potassium (Sorescu et al., 2020). Some of the ingredients in *Cucurbita moschata* prevent organisms that cause infectious diseases (Men et al., 2021). The ribosome inactivating proteins Moschatin and Cucurmosin from the mature seeds of pumpkin (C. moschata) have been reported to inhibit melanoma cell proliferation as well as leukaemia, lung adenocarcinoma and pancreas cancer cell proliferation (Sabbah et al., 2005).

2.7.7 Sunflower Seeds

Sunflower seeds are rich in phosphorous, magnesium, selenium, vitamins B-6 and E (Reddy, 2020). One ounce of dry-roasted sunflower seeds gives 49% of our daily need of vitamin E (Agarwal et al., 2020). Sunflower seeds are also a sources of folate, manganese, copper and zinc (Scientific, 2020). Sunflower oil increases body weight, total erythrocyte counts and hemoglobin concentration (Basak et al., 2017).

Herbs and spices have been used especially in this error of COVID 19 to fight the disease by boosting the immunity. Different studies have indicated the immune-modulatory effects of various spices and herbs. Few studies have been done in which different herbs

and spices have been combined and monitored on their effect on BMI, immune and hematological parameters. As a result, this study seeks to establish effect of Covi soup on the BMI, immunological and hematological parameters among PLWH. The ingredients of Covi soup include; Ginger, Garlic, Turmeric, Chilli pepper, Chia Seeds, Sunflower seeds and Butternut squash, all of which have been singly shown to have immune-modulatory effect in various studies. By combining these ingredients, it's highly likely that the resulting product will improve BMI, immunological and hematological parameters of PLWH.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Introduction

Chapter three presents the study design, materials and study methods.

3.2 Study Area

Kakamega County **(See appendix I)** is 3050.3 Km2 large with 12 sub counties. The County has Kakamega forest and receives adequate rainfall. It has a population of 1,843,320, 49% males and 51% females with 4.5% prevalence of PLWH (NACC, 2018). Kakamega County was purposively chosen because it is the second most populous county and it is among the eight counties that contribute 50% of PLWH in Kenya with a population of 48,752 PLWH. Of this, 3.4% are males and 5.6% are females. It is therefore important to combat incidences of COVID 19 infection in this vulnerable population in Kakamega County. The study site was KCTRH as it receives patients from versatile ethnic and geographical background and also because it is the only level 5 hospital in the county mandated to teach postgraduate students as well as conduct research.

3.3 Study design

3.3.1 Consort 2010 flow diagram

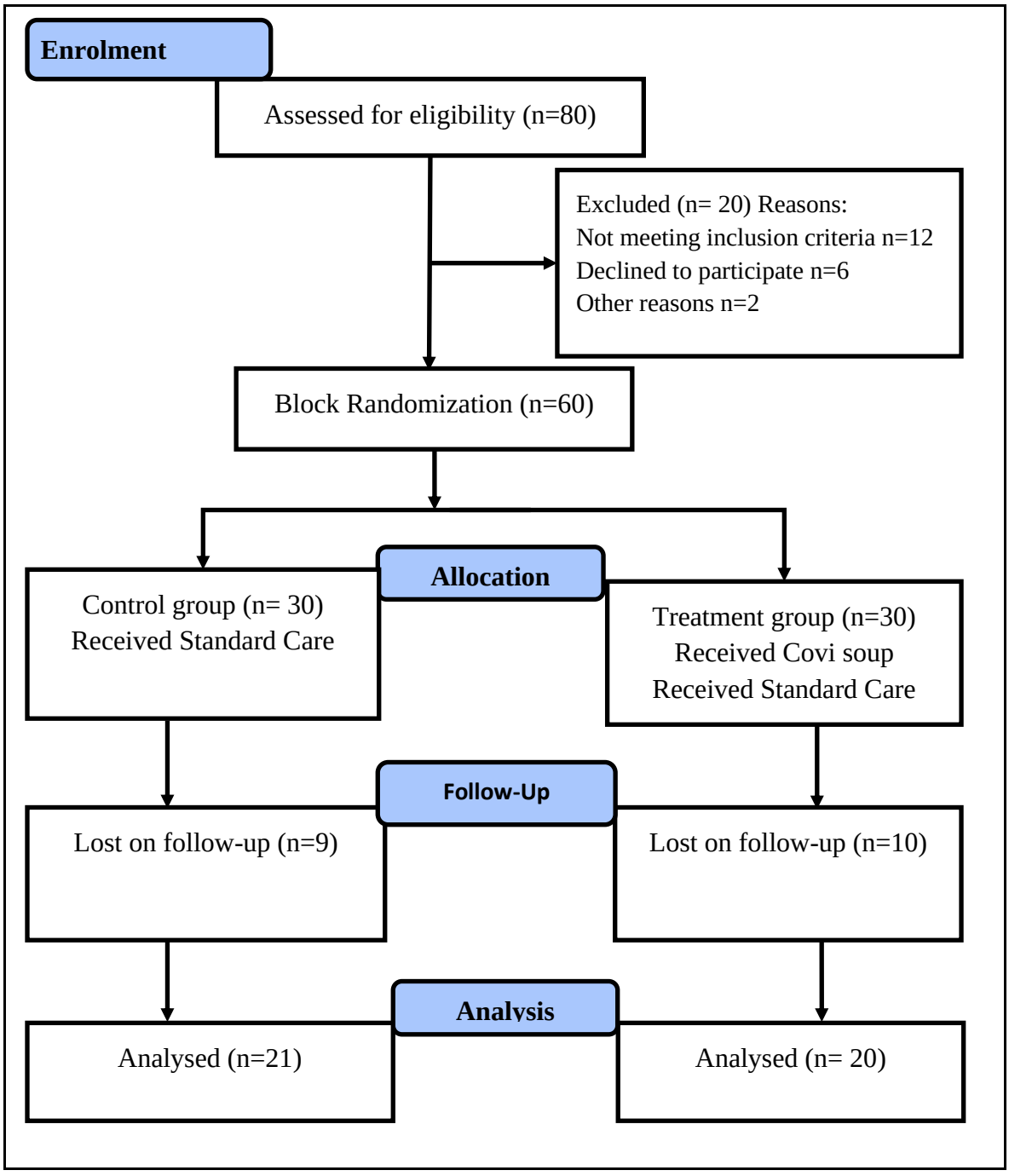


Figure 3. 1 A parallel group randomised control trial design

This was an open parallel RCT consisting of control group and treatment group (**See figure 3.1**). Both the participants and the researcher were aware of the intervention allocation. A total of 80 patients were systematically selected and assessed for eligibility. Out of which, 12 did not meet the inclusion criteria, 6 declined to participate and 2 were students attending boarding schools. The remaining 60 participants were randomized into either the control group or treatment group.

3.3.2 Randomization and Blinding

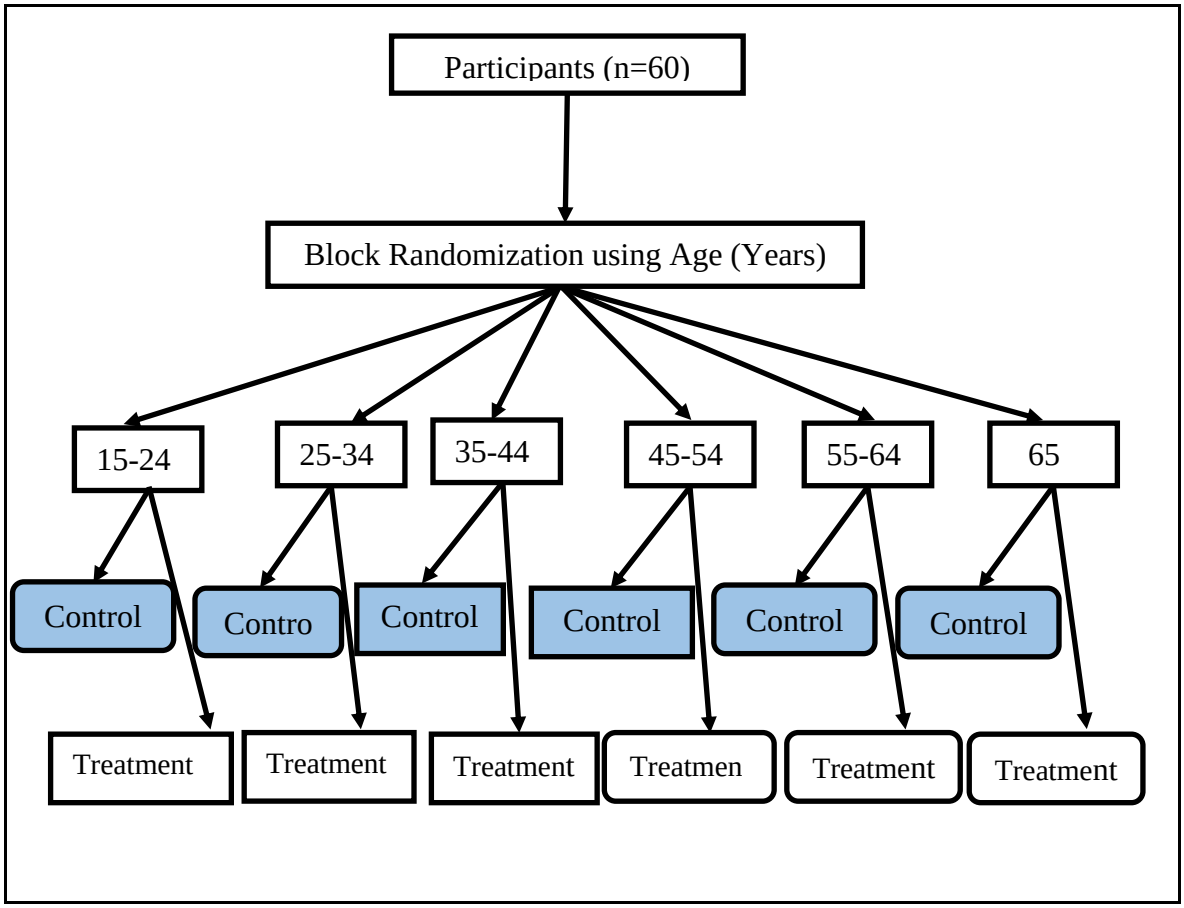


Figure 3. 2 Block randomization and allocating sequentially numbered opaque envelopes

Block randomization (**See figure 3.2**) placed the participants into 6 age blocks with an interval of 10. Within each age block formed, the participants were randomized into either the control group or treatment group by choosing sequentially numbered opaque and sealed envelopes. Randomized block design ensured that the participants in either the control group or treatment group had equal distribution of baseline characteristic.

3.3.3 Formulation and preparation of Covi soup

A local home grown solution, Covi soup was formulated by a research team in MMUST. Covi soup, made from a mixture of; dried ginger powder, dried garlic powder, roasted butternut squash powder, grounded chia seeds, grounded sunflower seeds, dried turmeric powder and chili pepper powder. The ingredients were collected in their natural form. Processing involved washing, sorting, peeling, dicing and drying on open aluminum trays in an oven at 50^0C until the ingredients were felt non-sticky. This was preceded by milling each ingredient separately using a milling machine to produce fine powder. The ingredients were then mixed in proportions that made the soup palatable. The mixed powder was sieved to obtain a fine powder. The powder was filled in small transparent polythene sachets each weighing 16.35g that were then sealed using electric manual sealer; then packed into larger packets containing 7 sachets each.

One serving of the soup (16.35 grams) contained (**See table 3.1**) 0.75g ginger, 0.5g garlic, 3.75g butternut, 0.5g chia seeds, 0.5g sunflower seeds, 0.25g turmeric and 0.1g chili pepper and 10g thickening agent.

Microbial analysis indicated 70 CFU/100µL meeting the WHO food safety standards. Nutrient analysis of Covi soup was done by the Kenya Bureau of Standards (KEBS) Covi

soup nutrient analysis report indicated that it is rich in vitamins, minerals and bioactive compounds (**See table 3.2**).

The soup preparation involved mixing 16.35g powder with 250 ml of cold water, bring to boil for 5 minutes and ready to serve while hot. The soup was consumed plain or accompanying other meals. Both male and female participants used 1 serving of the soup daily.

Table 3. 1:Composition of one serving of Covi soup

Ingredients of one serving of Covi soup		
Common name	**Scientific name**	**Quantity (g)**
Butternut squash	*Cucurbita moschata*	3.75
Ginger	*Zingiber officinalis*	0.75
Garlic	*Allium sativum*	0.5
Chilli pepper	*Capsaicin*	0.1
Sunflower seeds	*Helianthus annuus*	0.5
Chia seeds	*Salvia hispanica*	0.5
Turmeric	*Curcuma longa*	0.25
Wheat flour (thickening agent)	*Triticum aestivum*	10
Total		16.35

Table 3. 2 Kenya bureau of standards (KEBS) nutrient content analysis of Covi soup

Nutrient	In 16.35g (One serving)	In 100g
Calorie (Kj)	62.29	383.42
Fat (g)	0.66	4.032
Sodium (Mg)	5.46	33.43
Total CHO (g)	13.31	81.40
Dietary Fibre (g)	1.40	8.62
Sugar (g)	0.91	5.57
Protein (g)	2.09	12.79
Calcium (Mg/dl)	25.19	154.11
Iron (Mg)	1.08	6.60
Potassium (Mg)	166.39	1017.71
Choline (Mg)	1.87	11.46
Folate (Mcg)	30.04	183.72
Pantothenic (Mg)	0.21	1.23
Riboflavin (Mcg/l)	0.14	0.80
Thiamine (Ug/l)	0.12	0.74
Lutein & Zeaxanthin (Mg)	10.46	63.99
Vitamin C (Mg)	0.37	2.32
Vitamin B6 (Mg)	0.07	0.47
Copper (Mg)	0.059	0.36
Magnesium (Mg)	6.80	41.62
Manganese (Mg)	0.46	2.84
Phosphorus (Mg)	36.06	220.55
Selenium (Ug/dl)	4.89	29.93
Zinc (Mg/l)	0.23	1.38

3.4 Study population

The study Included PLWH attending CCC in the KCTRH. A total of 48,752 adults live with HIV in Kakamega County which translates to about 5.0% rate (NACC, 2018). Women prevalence is higher, 5.6% than men 3.4% (NACC, 2018).

3.4.1 Inclusion Criteria

1. PLWH aged 15-65 years; to ensure that the participants had the capacity to give informed consent. Informed consent for minors was sought from their parents or caregivers.
2. PLWH adhering to anti-HIV treatment for the past 3 years; to ensure there was consistency in using the drug regimen.
3. PLWH with a CD4+ count >200cells/μL; to ensure that the participants in the study were either in stage I or II of the HIV infection.
4. PLWH who consented; to ensure that all participants in the study agreed to participate.

3.4.2 Exclusion Criteria

1. PLWH on other medications other than ARTs; to ensure that no other factor contributed to changes in the CD4 + cell counts other than ARVs and Covi soup.
2. PLWH on ARVSaquinavir and Ritonavir; These medications interact with garlic a component in Covi soup reducing their efficiency.
3. Pregnant and Lactating women with HIV; They are vulnerable groups to partake a clinical trial.
4. PLWH attending the KCTRH CCC but come from the same household; To avoid aspects of sharing of information as well as the prescribed interventions in scenarios where two participants from either the intervention or control group came from the same household.
5. Participants who fell sick or became critically ill during the period of study.

3.5 Study variables

3.5.1 Dependent Variables

BMI, CD4 + cell count, Viral Load, Hb, MCV, MCH and MCHC were the dependent variables to be studied. WHO BMI cut off ranges was used: <18.5 was underweight, 18.5 to 24.9 was normal nutrition status, 25.0-29.9 was overweight and >30 was obese. HIV disease stages was defined as: Stage I HIV Infection; CD4+ count 500cells/µL, stage II HIV Infection; 350-499cell/µL, stage III HIV Infection/Advance HIV disease; 200-349cells/µL, Stage IV AIDS; <200cells/µL. Viral Load (VL) was measured in copies/millilitres of blood. High VL > 100,000copies/ml, Moderate VL 10,000–100,000copies/ml, Lower VL<10,000copies/ml and Undetectable VL was >20–75copies/ml. In both men and women, normal Hb was 12.0-17.0g/dl, mild anemia was 10.0-12.0g/dl, moderate anemia was <10.0-8.0g/l, and severe anemia was <8.0g/l. MCV was measured in femtoliters (fl); Normocytic 80-100fl; Microcytic <80fl and Macrocytic >100fl. MCH was measured in picograms (pg); Normochromic 27-34pg; Hypochromic <27pg and Hyperchromic >34pg. MCHC was measured in percentage (%); Normal 32%-36%; Decreased <32% and Increased >36%.

3.5.2 Intermediate variables

The intermediate variables that were included in all analysis were; Age, Gender, Occupation, Duration with Illness, Receipt of support, Type of medication, Number of household members and Dietary habits. These variables attributed to changes that occurred on the dependent variables; BMI (Kgs/$m^{2)}$, CD4 + cell count (cells/µL), VL (copies/ml), Hb (g/dl), MCV (fl), MCH (pg) and MCHC (%). However, in this study, in order to control the confounding factors, the intermediate variables were equally

distributed among the study groups. Hence the effect of intermediate variables was held constant.

3.5.3 Independent Variables

Covi soup intervention was the independent variable whose effect was measured on the dependent variables.

3.6 Sampling Design

Purposive sampling method was used in which the researcher makes a deliberate choice based on particular characteristics of the study area and study site (Rai, N & Thapa, B. 2015). Kakamega County was purposively chosen as the study area since it is ranked eighth in the top ten counties that contribute 50% of PLWH in Kenya. This high population of PLWH in the county puts the county at increased risk of suffering COVID 19 burden driven by HIV/AIDS. The study site which was KCTRH, was purposively chosen because it receives patients from versatile ethnic and geographical background. It is also the only level 5 hospital in the county mandated to offer teaching and research services to postgraduate students. Systematic random sampling was used to identify participants in which the researcher uses a fixed interval to select subjects (Elfil & Negida, 2017).

3.6.1 Sampling Strategy

Systematic random sampling was used to select the study participants. The sampling process took a one-month period. This ensured that there was no form of bias in selecting the study participants. PLWH attend clinic every Thursday of the week. The expected number of patients for each clinic visit was 100 patients, giving a sampling frame of 400 patients. The study needed 60 participants deriving an interval of 6, hence every 6^{th} patient attending CCC was asked if they were willing to participate. First participant was selected

at random but subsequent was selected at 6^{th} interval. 15 patients were sampled in four subsequent clinic visit day totalling to 60 participants as determined by the RCT formula.

3.7 Sample size determination

Determining the sample size with an RCT formula requires; P value (0.05), Study Power (1-β), Effect size (ES), Standard deviation (SD) and Dropout rate (d) (Gupta et al., 2016). The study adopted the study power, effect size, SD and dropout rate values of a similar previous study to calculate its sample size (Tshingani et al., 2017).

$n = 2 (Z \alpha + Z [1-\beta])^{2} \times SD^{2} / d^{2}$

$n = 2 (1.96 + 1.28)^{2} \times 3.3^{2}/1.95^{2} = 60$

Where:

n = sample size required (60)

Z_{α} = level of significance ($P < 0.05$)

1-β = study power (80% or 0.8)

SD = standard deviation (3.3)

d = effect size (1.95)

In this study, 60 participants were included, assuming 30 in control group and 30 in treatment group.

3.8 Data Collection

3.8.1 Data collection Instruments

Instruments included structured questionnaires (**See appendix VII**) and laboratory report forms (**See appendix VIII**).

3.8.1.1 Structured Questionnaire

Researcher administered questionnaire (**See appendix VII**) was used. Six sections were included: Section A was socio-demographics. The responses in this section were given by ticking the appropriate boxes; Section B gathered anthropometric measurements. Section C collected information on dietary practices; Section D elicited data on Hb, MCV, MCH and MCHC; Section E collected data on CD4+ cell count and VL; Section F captured information on the types of anti-HIV drugs the participants were using. The ART regimen were categorized as: AZT + 3TC + NVP, TDF +3TC + LPV/r, ABC + DDI + LPV/r. A single form questionnaire for each participant was used to record baseline and post study data.

3.8.1.2 Laboratory report forms

The laboratory report form (**See appendix VIII**) included data on CD4 + (cells/µL), VL (copies/ml), Hb (g/dl), MCV (fl), MCH (pg) and MCHC (%).

3.8.2 Data Collection Procedure

Data was collected by researcher and an assistant by first greeting the individual study participant for rapport creation. The participant was then informed objectives, risks and benefits involved. Assurance of confidentiality and anonymity was given to the participants. The participants were asked if they agree to participate, to sign consent form. The researcher and the assistant used an interview guide to ask questions as they filled up the questionnaire. A single form questionnaire for each participant was used to collect the baseline and post study data. Closed ended question format was used in which participants were asked to answer “yes” or “no”. It took approximately 20-30 minutes to complete administering the questionnaire for each participant.

3.8.2.1 Measurement of anthropometric parameters

The weight in Kgs and height in Cms was measured at baseline and post study using standard methods. Weight was measured with light clothing at 0.1kg accuracy using a SECA bathroom weighing scale. The height was taken in Cms using a SECA stadiometer and converted to meters (m). BMI was then calculated by dividing weight (Kgs) with height (m^2). This was redone two times and the mean recorded.

3.8.2.2 Collection of blood samples

A trained phlebotomist registered by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) withdrew blood sample from a vein in the participants' arm using a small needle and non-powdered sterile gloves. The participant felt a little sting when the needle got in and out. This took less than five minutes. The blood sample was collected in EDTA tubes and transported at ambient temperature. The blood sample was analyzed for CD4 +cell count, VL, Hb, MCV, MCH and MCHC within 48 hours. Samples were collected at BL and PS.

3.8.2.3 Determination of CD4+ cell count

Flow cytometry technique was used. The prepared samples were introduced into the cyflow counter machine. The cells were counted, categorized and displayed via histogram or dot plot. The report was printed in a laboratory report form.

3.8.2.4 Determination of VL

The blood sample was centrifuged at room temperature to separate the plasma. The plasma was transferred to a capped sterile polypropylene tube for a RT PCR RNA test to be conducted. The results were printed in a laboratory report form.

3.8.2.5 Determination of Hb, MCV, MCH and MCHC

The blood sample was analysed in a hematology automated analyser for a full blood count and the results were recorded in a laboratory report form.

3.8.3 Pre-test of Data Collection Instruments

Structured questionnaire was pretested on 10% of the study population for reliability and validity. In this study, 6 participants were chosen among the PLWH and subjected to the same questions within the same duration to gauge whether the questionnaire developed measured the indicated concept. A 0.8% reliability and validity index was generated. The six participants were excluded from the study. The anthropometric instruments; the bathroom scale and Stadiometer were calibrated to ensure that they give valid measurements consistently. A standard laboratory report form (**See appendix VIII**) was used and therefore needed no pretesting.

3.8.4 Baseline (BL) Phase

Study began with selection of study participants and collection of baseline data on 6th January 2022. The baseline data on socio-demographic characteristics, dietary practices, type of anti-HIV medication, BMI, CD4+ cell count, VL, Hb level, MCV, MCH and MCHC was collected from study participants in both groups. The researcher and the assistant collected information on socio-demographics, anthropometrics, dietary assessment and type of anti-HIV drugs. A trained and registered phlebotomist drew blood samples from the participants and analyzed the blood sample for CD4+ cell count, Hb g/dl, MCV, MCH and MCHC. The aim of this phase was to establish the baseline data on the BMI, immunological, hematological parameters of the study participants.

3.8.5 Administration of intervention

The control group was exclusively administered standard care while the treatment group was given Covi soup alongside standard care. The treatment group was assigned a different hospital return date to pick the Covi soup. The participants in both the control group and treatment group were given a hospital return date after 7 days to assess adherence of the administered care. Subsequent follow up was done through phone calls, short messages and home visits after every 3 days. Strict instruction was given to emphasize the importance of not sharing the Covi soup with other family members. The study participants were put in their respective care for a period of 90 days from their day of enrollment.

Standard care entailed nutrition counselling and anti-HIV drugs. Nutrition counseling was done by the researcher and the research assistant both who were certified nutritionists as recommended by the Kenya Nutritionists and Dietitians Institute (KNDI). The counseling was done in accordance with the Kenya National guidelines on Nutrition in HIV/AIDS with emphasis on the critical nutrition care practices. The participants were encouraged to consume locally available foods to meet their nutrients and energy needs. The participants were educated on strategies to meet energy needs, protein needs and micronutrients needs. The study participants were encouraged to adhere to their prescribed anti-HIV medication. The treatment group was administered standard care (Nutritional counselling and anti-HIV drugs) together with Covi soup intervention.

3.8.6 Post Study (PS) Phase

Post study data collection was done on 7th April 2022, which was 90 days from the day of enrollment. Data collection procedure was the same as the procedure used in collecting baseline data. Information on BMI was gathered by the researcher and the assistant. A trained and registered phlebotomist drew and analyzed blood samples for CD4+ cell count, VL, Hb, MCV, MCH and MCHC. The post study parameters were then compared to the baseline parameters to establish any significant difference at BL and PS within the respective study groups. This helped to determine the effects of Covi soup on BMI, immunological and hematological parameters of the study participants.

Table 3. 3 Summary of Baseline (BL), Intervention and Post Study (PS) phase

	Baseline	Administration of intervention	Post Study
Treatment group	Hb *(g/dl)* CD4+ cell count *(Cells/µL)* VL MCV MCH MCHC BMI *(kg/m2)*	Standard Care Prescribe Covi soup for 7 days Assess adherence of Covi soup after 7 days Prescribe Covi soup for 83 more days Make follow up calls and short messages to remind on strict adherence of the Covi soup and standard care after every 3 days	Hb *(g/dl)* CD4+ cell count *(Cells/µL)* VL MCV MCH MCHC BMI *(kg/m2)*
Control group	Hb *(g/dl)* CD4+ cell count *(Cells/µL)* VL MCV MCH MCHC BMI *(kg/m2)*	Standard care (exclusive) Assess adherence of administered care after 7 days Make follow up calls and short messages to remind on strict adherence to the standard care after every 3 days	Hb *(g/dl)* CD4+ cell count *(Cells/µL)* VL MCV MCH MCHC BMI *(kg/m2)*

3.9 Data analysis

Data management was achieved using SPSS at 95% level of confidence. Descriptive statistics analysed emerging themes and presented as mean and SD. Categorical variables were presented as frequencies and percentage. Inferential statistics was used to make generalization to the general population. T test analysed for significant difference in the study parameters at BL and PS in the control group and treatment group. Paired t test analysed effect of Covi soup on the study parameters.

Table 3. 4 Data analysis for each specific objective

	Objective(s)	Data analysis
1	To assess the effect of Covi soup on BMI of PLWH at KCTRH	Paired Sample T test
2	To determine the effect of Covi soup on CD4+ Cell Count of PLWH at KCTRH	Paired Sample T test
3	To establish the effect of Covi soup on VL of PLWH at KCTRH	Paired Sample T test
4	To ascertain the effect Covi soup on hematological parameters of PLWH at KCTRH	Paired Sample T test

3.10 Logistical and Ethical consideration

Research approval was obtained from MMUST directorate of postgraduate studies, Ethical approval cleared with MMUST Institutional Ethics Research Committee (IERC) reference number (MMUST/IERC/130/2023). Research permit obtained from National Commission for Science, Technology and Innovation (NACOSTI) with licence number (NACOSTI/P/23/28083). Trial was registered with Pan African Clinical Trial registry with a reference number (PACTR202307740330512). Permission was also sought from KCTRH ethical review committee and Kakamega County authorities. The researcher upheld the following principles; Autonomy in which the researcher allowed the participants to take part in the study without coercion; Beneficence; The study findings can be instrumental in informing decision makers on policy formulation; Confidentiality in which the names of the respondents were delinked from the questionnaires and unique numbers were assigned to conceal identity; Informed consent in which the study objectives were explained to the respondents before asking to take part; Justice in which participants were treated equally; Risks and benefits; Participants withdraw if uncomfortable .

CHAPTER FOUR

FINDINGS

4.1 Introduction

Chapter four presents findings of the study; response rate, demographic characteristics and analysis of data based on study objectives.

4.2 Response Rate

According to Bryman (2019) analysis of response rate is important in gauging the actual response against the expected response. This is shown in subsequent table.

Table 4. 1 Response Rate

Category	**Expected (N)**	**Percent**	**Actual (N)**	**Percent**
Control Group	30	100%	21	70%
Treatment Group	30	100%	20	67%
Total	60	100%	41	68%

The findings in table 4.1 show that, the study involved two categories of study participants namely control and treatment group. From 30 questionnaires for control group, 21 representing 70% were returned while 9 representing 30% were not returned. For the treatment group, out of the 30 expected responses, 20 representing 67% were retuned while 10 representing 33% were not. For both categories the response rate was high being above the threshold of 65% as in Kothari (2014). Therefore, the findings can be relied upon for conclusion and recommendation.

4.3 Socio-demographic Characteristics

4.3.1 Participants Age

Analysis of participants age for both control and treatment group is an important parameter in gauging the similarities and differences at baseline. The findings are as in figure 4.1.

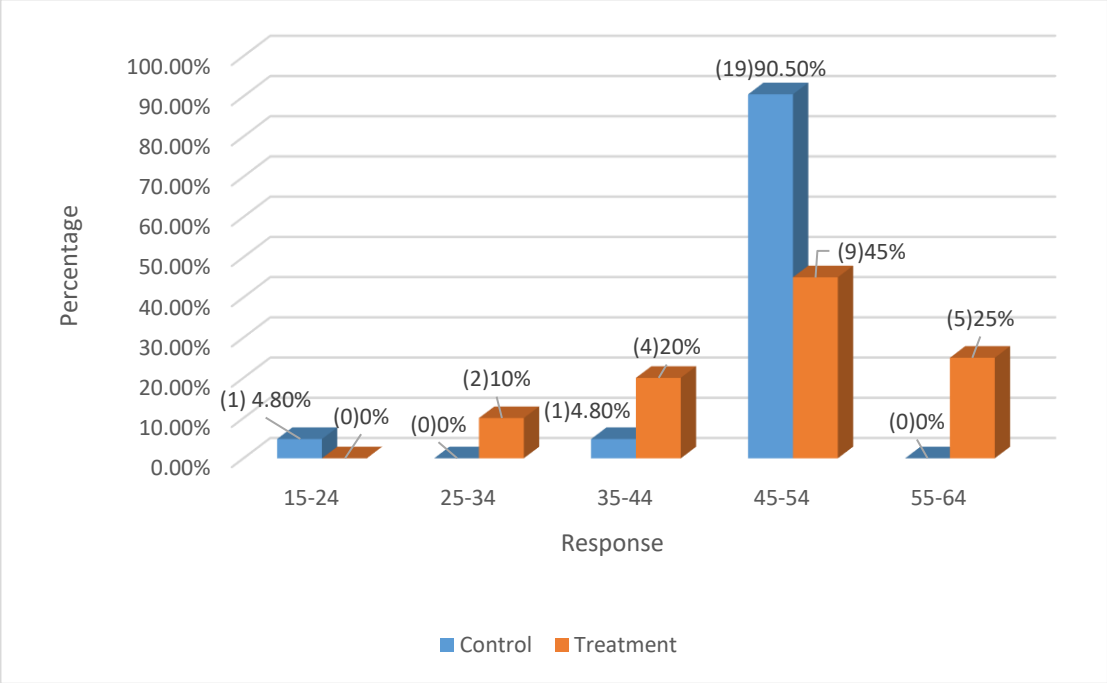


Figure 4. 1 Respondents Distribution by Age

The findings in figure 4.1 relate to distribution of participants by age for both control and treatment groups. The control group had (1) 4.8% response between the age category of 15-24 years. Between the ages 25-34 years, the treatment group had (2) 10% response. Control group and treatment group recorded (1) 4.8% and (4) 20.0% response for age category 35-44 years respectively. There was a high response recorded between the age category of 45-54 years in both groups. The treatment group had (5) 25% response of 55-64 years' category. The high response of 45-54 and 55-64 years' category could be

associated with the use of antiretroviral drugs which allow PLWH to have a prolonged life (Ahmed et al., 2021).

4.3.2 Respondent Gender

Gender is an important parameter in gauging any disparities in relation to control and treatment groups. The findings are as in the subsequent figure 4.2.

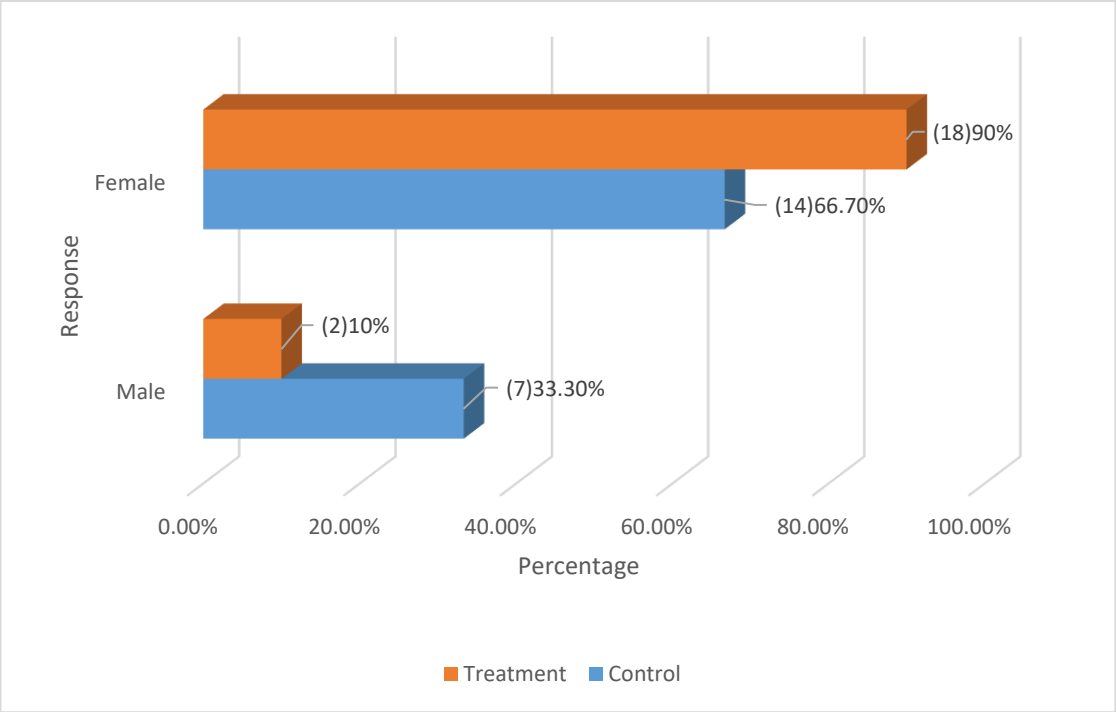


Figure 4. 2 Respondents Distribution by Gender

Figure above indicates that in both the control group and treatment group, there was a high percentage of female responses at (14) 66.7% and (18) 90.0% respectively. This high percentage of females is in accordance with the high prevalence of women living with HIV (UNAIDS, 2019).

4.3.3 Respondents Education Level

Analysis of level of education is important in determining how respondents vary in education levels for both control and treatment groups. The findings are as in table below.

Table 4. 2 Distribution by Education Level

Education level	Control (N)	Percent	Treatment (N)	Percent
Primary	10	47.6	11	55.0
Secondary	6	28.6	7	35.0
Tertiary	5	23.8	2	10.0
Total	21	100.0	20	100.0

Table 4.2 above indicates that both the control group and treatment group recorded a high percentage of primary education at (10) 47.6% and (11) 55.0% respectively. Both groups also had a lower percentage of tertiary education with control group recording (5) 23.8% and treatment group having (2) 10.0%.

4.3.4 Number of Household Members

Analysis of number of household members is important in determining the household size differences for both control and treatment groups. The findings are as in the subsequent figure 4.3.

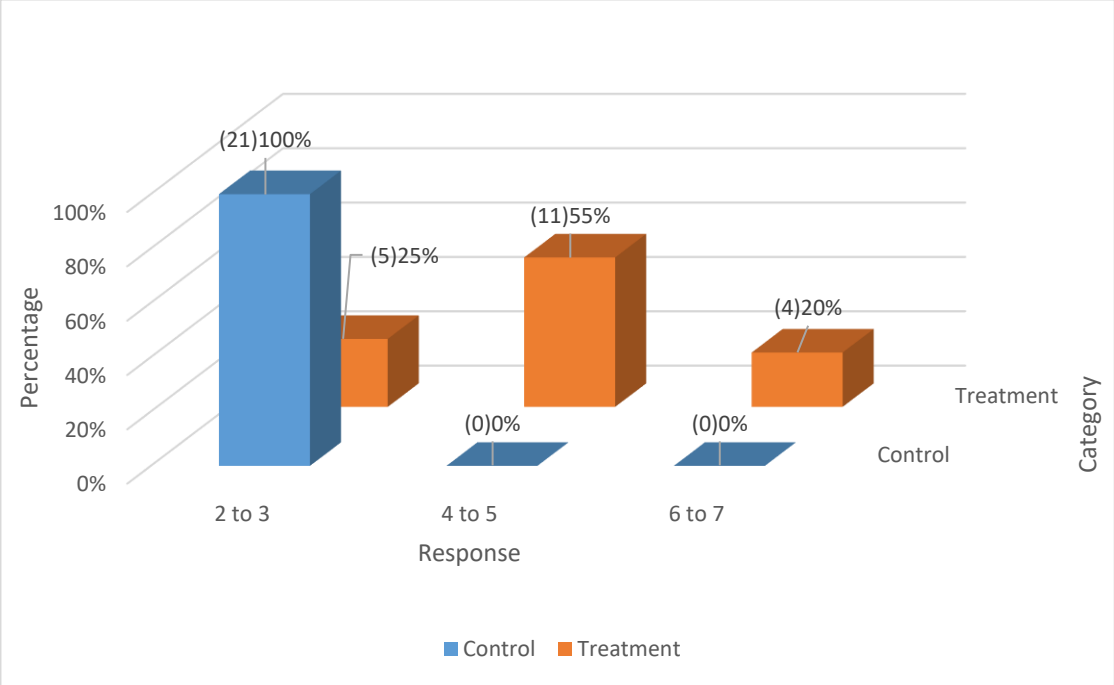


Figure 4. 3 Distribution by Number of Household Members

Figure above shows that (21) 100.0% of the control group had between 2-3 household members. Treatment group participants had majority of its participants with a family size of between 4-5 members at (11) 55.0%.

4.3.5 Duration with Infection

It is important to analyse the baseline distribution of duration of infection. The results are depicted in table below.

Table 4. 3 Distribution by Duration with infection

Duration with Infection (years)	Control (N)	Percent	Treatment (N)	Percent
1-5	21	100.0	19	95.0
6-10	-	-	1	5.0
Total	21	100.0	20	100

Table 4.3 above indicate that the control group had (21) 100.0% of the participants who had lived with HIV for 1-5 years. The treatment group also recorded (19) 95.0% participants who had lived with the infection for 1-5 years. This could be explained by the high infections that was reported in NACC 2017 report.

4.3.6 Type of Occupation

It is important to analyse the type of occupation. Occupation is a factor of good quality of life which is an intermediate factor in determining the BMI, immunological and hematological parameters in this study. Results are depicted in figure below.

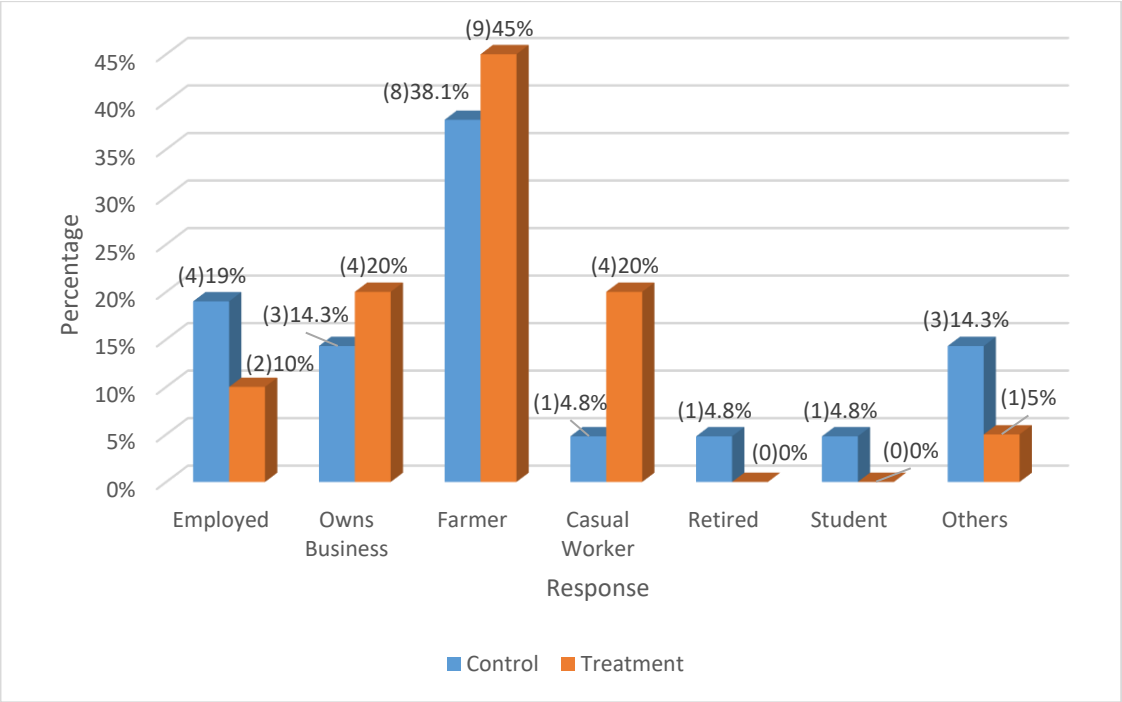


Figure 4. 4 Distribution by Type of Occupation

As depicted in figure 4.4 above, the control and treatment group recorded (4) 19.0% and (2) 10.0% employed responses respectively. Those who owned businesses were (3) 14.3% in control group and (4) 20.0% in treatment group. A high percentage response was seen in both the control group (8) 38.1% and treatment group (9) 45.0% having participants who were farmers. The casual workers, retired and student recorded the least with (1) 4.8% in the control group. Others referring to housewives, CHV and pastor recorded a (3) 14.3% in control group and (1) 5.0% in treatment group.

4.3.7 Receipt of Support

It is important to analyse whether the participants in both the control group and treatment group received any form of support or not. This is shown table below.

Table 4. 4 Distribution by Receipt of Support

Response	Control (N)	Percent	Treatment (N)	Percent
Yes	10	47.6	3	15.0
No	11	52.4	17	85.0
Total	21	100.0	20	100

Table 4.4 above shows that both the control group (10) 47.6% and treatment group (3) 15.0% reported a lower percentage receipt of support response. There was a high percentage response of no receipt of support in both groups, with control group recording (11) 52.4% and treatment group having (17) 85.0%.

4.3.8 Dietary practices

It is important to analyze whether the participants in both the control group and treatment group had similar dietary practices. This is shown in table below.

Table 4. 5 Distribution by Dietary practices

Food frequency in last 7 days	Control (N=21)		Treatment (N=20)		T Test P
	Mean	SD ±	Mean	SD±	
Bread	6.7	1.3	7.0	0.0	0.329
Meat	2.2	2.1	1.4	1.7	0.153
Poultry	1.4	1.7	0.9	0.9	0.273
Milk	5.1	2.6	4.9	3.0	0.743
Fruit	6.8	0.8	7.0	0.0	0.329
Legume	1.1	1.2	1.8	2.0	0.209
Fat	7.0	0.0	6.7	1.3	0.330

Table 4.5 above shows that the dietary practices of both the control group and treatment group were not significantly different. The mean frequency of bread, meat, poultry, milk, fruit, legume and fat consumption within seven days for the control group and treatment group was 6.7±1.3, 7.0±00 at p=0.329; 2.2±2.1, 1.4±1.7 at p=0.153; 1.4±1.7, 0.9±0.9 at p=0.273; 5.1±2.6, 4.9±3.0 at p=0.743; 6.8±0.8, 7.0±0.0 at p=0.329; 1.1±1.2, 1.8±2.0 at p=0.209 and 7.0±0.0, 6.7±1.3 at p=0.330. The similarities in dietary practices could be

attributed to the fact that all PLWH under treatment are subjected to nutrition counselling and education to help them have good nutrition status and slow progression of the disease.

4.3.9 Type of treatment

It is important to analyze whether participants were using similar type of medication. This is shown in the table below.

Table 4. 6 Distribution by Type of Medications

Type of Medication	Control Group (21)	Percent	Treatment Group (20)	Percent
ABC, 3TC	1	4.8	0	-
TDF, 3TC, AZT	1	4.8	1	5.0
TDF, 3TC, DTG	12	57.1	17	85.0
TDF, 3TC, EFV	7	33.3	2	10.0
Total	21	100	20	100

Table 4.6 above indicates that (1) 4.8% of participants in control group used ABC, 3TC type of medication. There was only 1 participant 4.8% and 5.0% in the control and treatment group using TDF, 3TC, AZT type of medication. Majority of the participants in both groups were using TDF, 3TC, DTG type of medication (12) 57.1% and (17) 85% respectively. And (7) 33.3% and (2) 10.0% of the participants were using TDT,3TC, EFV in the control group and treatment group.

4.4 Objective 1: Effect of Covi soup on BMI of PLWH in KCTRH

Table 4. 7 Independent t test and Paired t test of mean BMI

	Control Group N=21		Paired T test	Treatment Group N=20		Paired T test	T test *P*	
	BL	PS	*P*	BL	PS	*P*	BL	PS
BMI (kg/m^2)	23.9 ± 4.3	24.0 ± 4.2	0.092	27.3 ± 5.4	27.1 ± 5.3	0.149	0.031	0.046
Change	+0.1			-0.2				

Table above shows baseline mean BMI for control group and treatment group was 23.9 ± 4.3 and 27.3 ± 5.4 respectively at p=0.031 indicating that the means were significantly different. The post study mean BMI was 24.0 ± 4.2 for the control group and 27.1 ± 5.3 for the treatment group at p=0.046 indicating that the means were significantly different. The control group baseline mean BMI was 23.9 ± 4.3 and 24.0 ± 4.2 post study p=0.092. No significant effect in mean BMI at baseline and post study was observed in control group. Treatment group baseline mean BMI was 27.3 ± 5.4 and treatment group post study mean BMI was 27.1 ± 5.3 at p=0.149. No significant effect was observed in mean BMI at baseline and post study in both groups.

4.5 Objective 2: Effect of Covi soup on CD4 + cell count of PLWH in KCTRH

Table 4. 8 Independent t test and paired t test of mean CD4+ Cell Count

	Control Group N=21		Paired T test	Treatment Group N=20		Paired T test	T test *P*	
	BL	PS	*P*	BL	PS	*P*	BL	PS
CD4 + cell count (cells/ml)	440.4 ± 199.7	449.4 ± 276.7	0.838	417.6 ± 165.3	538.2 ± 199.3	0.012	0.694	0.248
Change	+9.0			+120.6				

Table 4.8 depicts the baseline mean CD4+ count for both the control group and treatment group as 440.4 ± 199.7 and 417.6 ± 165.3 respectively at p=0.694. The baseline mean CD4+ count for both groups was not significantly different. The CD4+ count was 449.4 ± 276.7 for control group and 538.2 ± 199.3 for treatment group at p=0.248 indicating no significant difference in mean CD4+ count for both groups at post study. In the control group, the mean CD4+ count at baseline was 440.4 ± 199.7 and the mean CD4+ count post study was 449.4 ± 276.7 at p=0.838. No significant effect was observed in mean CD4+ count at baseline and post study in control group. Treatment group baseline mean CD4+ count was 417.6 ± 165.3 and post study mean CD4+ count was 538.2 ± 199.3 at p=0.012. A significant effect was observed in the mean CD4+ count at post study in the treatment group.

4.6 Objective 3: Effect of Covi soup on VL of PLWH in KCTRH

Table 4. 9 Independent t test and paired t test mean VL

	Control Group N=21		Paired T test	Treatment Group N=20		Paired T test	T test *P*	
	BL	PS	*P*	BL	PS	*P*	BL	PS
VL	86.3 ± 48.2	76.8 ± 41.8	0.051	97.3 ± 76.7	95.0 ± 73.5	0.298	0.587	0.332
Change	-9.5			-25.1				

Table 4.9 depicts that the baseline mean VL for control group and treatment group was 86.3 ± 48.2 and 475.2 ± 1683.5 respectively at p=0.587. No significant difference was observed in baseline mean VL in both groups. In table 4.9 above, the post study mean VL for control group and treatment group was 76.8 ± 41.8 and 450.1 ± 1578.7 at p=0.332 indicating no significant difference in mean VL for both groups at post study. The table also indicates that mean VL at baseline was 86.3 ± 48.2 and mean VL post study was 76.8 ± 41.8 in the control group at p=0.051. Baseline mean VL was 475.2 ± 1683.5 and mean VL post study was 450.1 ± 1578.7 in treatment group at p=0.298. No significant effect was observed in mean VL at baseline and post study in both groups.

4.7 Objective 4: Effect of Covi soup on hematological parameters of PLWH in KCTRH

4.7.1 Effect of Covi soup on Hb of PLWH in KCTRH

Table 4. 10 Independent t test and paired t test mean Hb

	Control Group N=21		Paired T test	Treatment Group N=20		Paired T test	T test P Value	
	BL	PS	P Value	BL	PS	P Value	BL	PS
Hb (g/dl)	12.6 ± 2.0	12.5 ± 2.1	0.116	12.6 ± 1.4	13.6 ± 1.8	0.010	0.959	0.073
Change	-0.1			+1.0				

Table above shows baseline mean Hb for control group was 12.6 ± 2.0 and treatment group 12.6 ± 1.4 had no significant difference at p=0.959. In table 12 above, the post study means Hb of the control group 12.5 ± 2.1 and treatment group 13.6 ± 1.8 had no significant difference at p=0.073. Table above indicate the control group mean Hb was 12.6 ± 2.0 at baseline and mean Hb was 12.5 ± 2.1 at post study at p=0.116. No significant effect was observed in the baseline and post study mean Hb in the control group. Treatment group had baseline mean Hb of 12.6 ± 1.4 and post study mean Hb of 13.6 ± 2.0 at p=0.010**.** A significant effect in the mean Hb at baseline and post study was recorded in the treatment group.

4.7.2 Effect of Covi soup on MCV of PLWH in KCTRH

Table 4. 11 Independent t test and paired t test mean MCV

	Control Group N=21		Paired T test	Treatment Group N=20		Paired T test	T test P Value	
	BL	PS	P Value	BL	PS	P Value	BL	PS
MCV (fl)	66.4 ± 5.6	66.3 ± 5.6	0.635	67.5 ± 2.8	68.4 ± 4.4	0.122	0.434	0.191
Change	-0.1			+0.9				

In table above, the baseline mean MCV for the control group and treatment group was 66.4 ± 5.6 and 67.5 ± 2.8 respectively, at p=0.434 indicating no significant difference of the baseline mean MCV. At post study, mean MCV for the two groups was 66.3 ± 5.6 and 68.4 ± 4.4 respectively at p=0.191 showing no significant difference. The findings show the baseline mean MCV was 66.4 ± 5.6 and the post study mean MCV was 66.3 ± 5.6 at p=0.635 in control group. Treatment group baseline mean MCV was 67.5 ± 2.8 and post study mean MCV was 68.4 ± 4.4 at p=0.122. No significant effect was observed in the mean MCV at baseline and post study in both groups.

4.7.3 Effect of Covi soup on MCH of PLWH IN KCTRH

Table 4. 12 Independent t test and paired t test mean MCH

	Control Group N=21		Paired T test	Treatment Group N=20		Paired T test	T test P Value	
	BL	PS	P Value	BL	PS	P Value	BL	PS
MCH (pg)	26.7 ± 3.0	26.7 ± 3.1	0.870	26.5 ± 2.1	27.2 ± 2.5	0.352	0.806	0.604
Change	0.0			+0.7				

As depicted in table above, no significant difference was observed in baseline mean MCH for control group and treatment group; 26.7 ± 3.0 and 26.5 ± 2.1 at p=0.806 respectively. No significant difference was also recorded in post study mean MCH for control group 26.7 ± 3.1 and treatment group 27.2 ± 2.5 at p=0.604. In control group, the baseline mean MCH was 26.7 ± 3.0 and post study mean MCH was 26.7 ± 3.1 at p=0.870. Treatment group recorded mean MCH of 26.5±2.1 at baseline and mean MCH of 27.2 ± 2.5 post study at p=0.352. No significant effect was observed in the mean MCH at baseline and post study in both groups.

4.7.4 Effect of Covi soup on MCHC of PLWH in KCTRH

Table 4. 13 Independent t test and paired t test mean MCHC

	Control Group N=21		Paired T test	Treatment Group N=20		Paired T test	T test P Value	
	BL	PS	P Value	BL	PS	P Value	BL	PS
MCHC (%)	40.2 ± 2.1	40.3 ± 2.7	0.800	39.3 ± 3.2	39.7 ± 1.8	0.528	0.268	0.428
Change	+0.1			+0.4				

Table above shows baseline mean MCHC for control group was 40.2 ± 2.1 and for treatment group was 39.3 ± 3.2 at p=0.268 indicating no significant difference in the baseline mean MCHC for the two groups. Table 4.13 also indicates no significant difference observed in post study MCHC means for the control group 40.3 ± 2.7 and treatment group 39.7 ± 1.8 at p=0.428. Control group had mean MCHC of 40.2 ± 2.1 at baseline and mean MCHC of 40.3 ± 2.7 post study at p=0.800. Treatment group had a baseline mean MCHC of 39.3 ± 3.2 and mean MCHC of 39.7 ± 1.8 post study at p=0.528. No significant effect in mean MCHC at baseline and post study was observed in both groups.

CHAPTER FIVE

DISCUSSION

5.1 Introduction

Chapter five focuses on discussing results in order of study objectives and compares them to findings of other studies.

5.2 Socio-demographic characteristics PLWH in KCTRH

Socio-demographic characteristics play a big role in adherence to treatment. As earlier reported, majority of the study participants were within 45-54 years. This is similar to a study done in China that found middle aged HIV/AIDS had more incidence (Xu et al., 2019). The similarity could be attributed by the period in which the study was conducted from 2004 to 2016 a case in point while Kenya reported high new infections (NACC, 2017). Higher percentage of females with HIV was reported in both the control group and treatment group. This is in agreement with another study that found HIV burden was higher in women (Girum et al., 2018). This similarity is attributed to the geographical location of both studies that has more women 15+ years living with HIV (UNAIDS, 2019), (Awofala & Ogundele, 2018). These is also explained by the differences in biology and social behaviour between males and females that attributes to inequalities on women's risk (Adediran et al., 2016). A majority of participants had acquired primary education while tertiary education was least acquired. This contrasts to a study in Bangladesh that had 29.9% participants with primary education and 35.9% with secondary education, however, tertiary education was the least at 8.2% (Yaya et al., 2016), (Joshua et al., 2021). This could be attributed by including only women in the study. The current study findings indicate that majority of the participants did not receive any form of support, a factor that reduces the level of depression among PLWH (Matsumoto et al. 2017, n.d.). Psychosocial

and spiritual support contribute to a better Quality of life of PLWH (Hipolito et al., 2017), (Ahmed et al., 2022). Housing is a significant factor to consistent adherence to ARVs and sustained VL (Aidala et al., 2016). The study findings indicate that majority of the participants had small family sizes consisting of between 2-5 members.

5.3 Effect of Covi soup on BMI of PLWH in KCTRH

The -0.2 change in the mean BMI of the treatment group indicates that Covi soup treatment had a positive effect in lowering the high BMI scores of the participants although not to a significant level $p = 0.149$. This agrees with a study on curcumin supplements on metabolic parameters of PLWHA that found no effect on body composition (Silva et al., 2019). This similarity could be due to the curcumin also known as turmeric that was used in both studies. However, the current finding contrasts with an RCT among Indian women living with HIV in which there was a significant increase in the lean mass from protein supplement and nutrition education (Carpenter et al., 2021). This difference could be due to the type of interventions administered to the participants as well as the differences in the variables of study; BMI and lean body mass. Another contrasting finding in an RCT reported that nutritional intervention have a significant role in reducing cardio metabolic parameters including BMI (Aparecida Silveira et al., 2020). Systematic review and meta-analysis also reported that protein-energy fortified macronutrient supplement positively influences nutritional status in PLWH (Hong et al., 2018). The types of nutritional interventions used in these studies vary in their composition with the current Covi soup ultimately causing the differences in the results.

5.4 Effect of Covi soup on CD4+ count of PLWH in KCTRH

In the treatment group, there was a +120.6 change at p=0.012 indicating a significant effect in mean CD4+ count at post study, hence Covi soup had a positive effect on the CD4+ count of PLWH. This finding correlate to another study which reported that nutrition interventions and supplementation are able to improve CD4+ cell count among women with HIV (Nyamathi et al., 2018). An RCT conducted in Rwanda reported a significant reduction on the CD4+ cell count decline (Kamwesiga et al., 2015), (Muzembo et al., 2019). Protein energy fortified macronutrient supplement was effective in improving immune responses among PLWH (Hong et al., 2018). *Moringa oleifera* Lam. Leaves were also found to improve immune response of PLWH (Gambo et al., 2022), (Twinomujuni et al., 2022). Another study reported similar findings on the beneficial effect of carrot-ginger blend on the immune status of PLWH (Joshua et al., 2021b). The similarities in these study findings could resonate from the nutrition interventions and supplements administered which contain bioactive compounds and nutrients able to improve the CD4+ count.

5.5 Effect of Covi soup on VL of PLWH in KCTRH

The intra group baseline and post study comparison show that the treatment group had -25 change at p=0.298 indicating that these change was not statistically significant. Hence, Covi soup had no significant effect on the VL of PLWH. This finding is similar to another systematic review on selenium supplements that reported no effect viral load (Muzembo et al., 2019). Leaf concentrate and skimmed milk powder were found not to have any effect VL(Collin et al., 2016). This was also true in the study of effect of *Moringa oleifera* leaf powder on VL (Gambo et al., 2021), (Kamwesiga et al., 2015). However, Artemisia annua with Moringa oleifera Lam, have been found to have a significant improvement on

VL suppression. This could be due to the combination of two herbal medicines unlike when using *Moringa oleifera* alone (Twinomujuni et al., 2022). This finding is also contrasting to another study that found protein-energy fortified macronutrient positively influence immunological response in PLWH (Hong et al., 2018). This difference in findings could be contributed with the different nutrient composition of the interventions administered.

5.6 Effect of Covi soup on Hematological parameters of PLWH in KCTRH

In Kenya, microcytic and hypochromic anaemia are the most common erythrocytic deviations among HIV infected patients (Abonyo, Shaviya, et al., 2020). Study findings indicate that control group had a -0.1 change at p=0.116 and treatment group had +0.1 change at p=0.010. This indicates that Covi soup had a significant effect on the Hb of PLWH. The baseline and post study mean MCV was accompanied by -0.1 change at p=0.635 in control group and +0.9 change at p=0.122 in treatment group indicating no significant effect. Hence, Covi soup did not have an effect on the MCV of PLWH. The baseline and post study mean MCH was accompanied by +0.1 change in control at p=0.870 and +0.7 change in treatment at p=0.159. No significant effect was observed in both groups indicating that Covi soup had no effect on the MCH of PLWH. The mean MCHC change was +0.1 at p=0.800 in control group and +0.4 at p=0.528 in the treatment group, hence no statistically significant evidence to show that Covi soup has an effect on the MCHC of PLWH. These findings are contrasting to a previous study which reported an improvement of the MCV, MCH and RBC after treatment with vitamin B 12 and folate (Rezaei et al., 2016). The differences in the results could be attributed to the type of interventions used, frequency and dosage of the interventions as well as differences in the study populations.

CHAPTER SIX

CONCLUSION AND RECOMMENDATION

6.1 Introduction

Chapter six presents' conclusions as per the objectives and recommendations for policy makers, practice and future research.

6.2 Conclusions

Study conclusions are based on objectives and research questions of the study.

6.2.1 Effect of Covi soup on BMI of PLWH in KCTRH

The first research question was what is the effect of Covi soup on the BMI of PLWH in KCTRH? According to the current study findings, there was a positive change in the mean BMI of the treatment group though not significant. Therefore, we conclude that there was no significant effect that was observed in the mean BMI at baseline and post study in treatment group. We therefore conclude that Covi soup had no significant effect on the BMI of PLWH in KCTRH.

6.2.2 Effect of Covi soup on CD4 + count of PLWH at KCTRH

The second research question was what is the effect of Covi soup on the CD4+ count of PLWH in KCTRH? Study findings indicate there was a positive change in mean CD4+ count in treatment group which was significant. Therefore, we conclude that Covi soup had a significant effect on CD4+ count in treatment group. We therefore conclude that Covi soup had a significant effect on the CD4+ count of PLWH in KCTRH.

6.2.3 Effect of Covi soup on VL of PLWH in KCTRH

The third research question was what is the effect of Covi soup on the VL of PLWH in KCTRH? Study findings show no significant effect in baseline and post study mean VL of the treatment group, hence, Covi soup had no significant effect on VL of PLWH in KCTRH.

6.2.4 Effect of Covi soup on Hematological parameters of PLWH in KCTRH

6.2.4.1 Effect of Covi soup on Hb of PLWH in KCTRH

Study findings showed a significant positive change in the mean Hb within the treatment group. Hence we can ascertain that Covi soup had a significant effect on the Hb of PLWH in KCTRH.

6.2.4.2 Effect of Covi soup on MCV of PLWH in KCTRH

Study findings indicate no significant effect in the post study mean MCH of treatment group. We therefore conclude that Covi soup had no significant effect on the MCV of PLWH in KCTRH.

6.2.4.3 Effect of Covi soup on MCH of PLWH in KCTRH

The post study mean MCH in treatment group showed no significant change. We therefore conclude that Covi soup had no significant effect on the MCH of PLWH in KCTRH.

6.2.4.4 Effect of Covi soup on MCHC of PLWH in KCTRH

Study findings showed no significant change in MCHC in treatment group. We therefore conclude that Covi soup had no significant effect on MCHC of PLWH in KCTRH.

6.3 Recommendations

The recommendations hereunder are made for different stakeholders and information consumers.

6.3.1 Recommendations for policy makers

Covi soup had a significant effect on the CD4 + cell count and Hb of PLWH. Therefore, the Ministry of Health (MoE) through policy makers can adapt this innovative ingredient and promote its use at clinical level as well as community level as a food by prescription (FBP) among PLWH. This is highly recommended so as to improve the already compromised CD4 + cell count and Hb status of PLWH.

6.3.2 Recommendations for practice

Covi soup has proven efficient in boosting the CD4+ cell count and Hb level of PLWH at KCTRH. Based on this novel information, health practitioners in the KCTRH should educate and counsel on the use of Covi soup among PLWH. Nurses and nutritionists to spearhead in training PLWH attending the KCTRH CCC on the homebased preparation and use of all the ingredients used to prepare Covi soup that are locally available. Habitual use of these ingredients will ensure an improved immunological and hematological status of PLWH which is key in the fight against COVID 19.

6.3.3 Recommendations for further research

To ascertain the effect of Covi soup on CD4+ cell count and Hb of PLWH, we recommend a cross over RCT to be done with an increased serving of Covi soup administered for a longer study period.

REFERENCES

Abonyo, C., Collins, A., Nathan, S., Valentine, B., & Tom, W. (2020). *Anemia Burden, Types and Associated Risk Factors among Kenyan Human Immunodeficiency Virus-1 and Mycobacterium Tuberculosis Co-Infected Injection Substance Users*.

Abonyo, C., Shaviya, N., Budambula, V., & Were, T. (2020). Anemia Burden, Types and Associated Risk Factors among Kenyan Human Immunodeficiency Virus-1 and Mycobacterium Tuberculosis Co-Infected Injection Substance Users. *Ethiopian Journal of Health Sciences*, *30*(5), 661–670. https://doi.org/10.4314/ejhs.v30i5.4

Abue, A. D., Amodu, B., & Akukwu, D. C. A. (2021). Using African alternative medicine to curb Covid-19: A case study of SAAAB, SAABFAT6, and SAABMAL HERBAL SUPPLEMENTS. *Researchgate.Net*, *January*. https://doi.org/10.9790/0853-1905060108

Adediran, A., Osunkalu, V., Wakama, T., John-Olabode, S., Akinbami, A., Uche, E., & Akanmu, S. (2016). Impact of HIV Infection and Zidovudine Therapy on RBC Parameters and Urine Methylmalonic Acid Levels. *Interdisciplinary Perspectives on Infectious Diseases*, *2016*, e5210963. https://doi.org/10.1155/2016/5210963

Adepoju, P. (2020). Feature Tuberculosis and HIV responses threatened by COVID-19. *The Lancet HIV*, *7*(5), e319–e320. https://doi.org/10.1016/S2352-3018(20)30109-0

Adjei, G., Enuameh, Y. A., & Thomford, N. E. (2021). Prevalence of COVID-19 genomic variation in Africa: A living systematic review protocol. *JBI Evidence Synthesis*, *20*(1), 158–163. https://doi.org/10.11124/JBIES-20-00516

Agarwal, S., Saha, S., Deb, T., & Darbar, S. (2020). *Immunity augmenting food supplements for susceptible individuals in combating pandemic COVID-19 (Review)*. 79–88. https://doi.org/10.5281/zenodo.3880638

Ahmed, A., Dujaili, J. A., Jabeen, M., Umair, M. M., Chuah, L.-H., Hashmi, F. K., Awaisu, A., & Chaiyakunapruk, N. (2022). Barriers and Enablers for Adherence to Antiretroviral Therapy Among People Living with HIV/AIDS in the Era of COVID-19: A Qualitative Study From Pakistan. *Frontiers in Pharmacology*, *12*. https://www.frontiersin.org/articles/10.3389/fphar.2021.807446

Ahmed, A., Saqlain, M., Bashir, N., Dujaili, J., Hashmi, F., Mazhar, F., Khan, A., Jabeen, M., Blebil, A., & Awaisu, A. (2021). Health-related quality of life and its predictors among adults living with HIV/AIDS and receiving antiretroviral therapy in Pakistan. *Quality of Life Research*, *30*(6), 1653–1664. https://doi.org/10.1007/s11136-021-02771-y

Aidala, A. A., Wilson, M. G., Shubert, V., Gogolishvili, D., Globerman, J., Rueda, S., Bozack, A. K., Caban, M., & Rourke, S. B. (2016). Housing Status, Medical Care, and Health Outcomes Among People Living with HIV/AIDS: A Systematic Review. *American Journal of Public Health*, *106*(1), e1–e23. https://doi.org/10.2105/AJPH.2015.302905

Akash, N., Leslie Rani, S., & Brundha, M. P. (2020). Awareness on benefits of chia seeds among college students. *Drug Invention Today*, *14*(2), 348–351.

Akbari, M., Fararouei, M., Haghdoost, A. A., Gouya, M. M., & Kazerooni, P. A. (2019). *Survival and associated factors among people living with HIV / AIDS: A 30 - year national survey in Iran*. https://doi.org/10.4103/jrms.JRMS

Alhazmi, H. A., Najmi, A., Javed, S. A., Sultana, S., Al Bratty, M., Makeen, H. A., Meraya, A. M., Ahsan, W., Mohan, S., Taha, M. M. E., & Khalid, A. (2021). Medicinal Plants and Isolated Molecules Demonstrating Immunomodulation Activity as Potential Alternative Therapies for Viral Diseases Including COVID-19. *Frontiers in Immunology*, *12*(May), 1–24. https://doi.org/10.3389/fimmu.2021.637553

Alkenany, M. H., Al-Ardhi, S. A. A., & Al-Gharawi, J. K. (2021). Effect of Chia Seeds Water Extract on Some Physiological Traits of Broiler. *IOP Conference Series: Earth and Environmental Science*, *923*(1), 012045. https://doi.org/10.1088/1755-1315/923/1/012045

Anjulo, T., Id, A., Koyra, M. M., Gidebo, K. D., & Abiso, L. (2019). *Anemia and its associated factors among adult people living with human immunodeficiency virus at Wolaita Sodo University teaching referral hospital*. *2*, 1–13.

Aparecida Silveira, E., Falco, M. O., Santos, A. S. E. A. de C., Noll, M., & de Oliveira, C. (2020). Nutritional Intervention Reduces Dyslipidemia, Fasting Glucose and Blood Pressure in People Living with HIV/AIDS in Antiretroviral Therapy: A Randomized Clinical Trial Comparing Two Nutritional Interventions. *Nutrients*, *12*(10), 2970. https://doi.org/10.3390/nu12102970

Awofala, A. A., & Ogundele, O. E. (2018). HIV epidemiology in Nigeria. *Saudi Journal of Biological Sciences*, *25*(4), 697–703. https://doi.org/10.1016/j.sjbs.2016.03.006

Aynalem, Y. A., Shibabaw Shiferaw, W., & Woldiye, Z. (2020). Prevalence of Anemia and Its Associated Factors in Antiretroviral-Treated HIV/AIDS-Positive Adults from 2013 to 2018 at Debre Berhan Referral Hospital, Ethiopia. *Advances in Hematology*, *2020*. https://doi.org/10.1155/2020/2513578

Barr, D., Garnett, G. P., Mayer, K. H., & Morrison, M. (2021). *Key populations are the future of the African HIV / AIDS pandemic*. *24*, 1–4. https://doi.org/10.1002/jia2.25750

Basak, A., La, B., Ahmad, N., & Rafiq, K. (2017). *Effect of sunflower oil supplementation in feed on body weight and hematobiochemical parameters in mice*. *28*(1), 36–41.

Bei, Y. (2017). Obesity in HIV. *Physiology & Behavior*, *176*(3), 139–148. https://doi.org/10.1007/s11904-020-00483-5.OBESITY

Berhane, Y., Haile, D., & Tolessa, T. (2020). Anemia in hiv/aids patients on antiretroviral treatment at ayder specialized hospital, Mekele, Ethiopia: A case-control study. *Journal of Blood Medicine*, *11*, 379–387. https://doi.org/10.2147/JBM.S275467

Bhardwaj, S., Almaeen, A., Wani, F. A., & Thirunavukkarasu, A. (2020). *Hematologic derangements in HIV / AIDS patients and their relationship with the CD4 counts: A cross-sectional study*. *13*(4), 756–763.

Care, P., Sah, S. K., Dahal, P., Tamang, G. B., Mandal, D. K., Shah, R., & Pun, S. B. (2020). *Prevalence and Predictors of Anemia in HIV- Infected Persons in Nepal*. 193–200.

Care, P., Zenebe, W. A., Anbese, A. T., & Tesfaye, T. S. (2019). *Anemia And Associated Factors Among Adult People Living With HIV / AIDS Receiving Anti-Retroviral Therapy At Gedeo Zone, SNNPR* ,. 351–356.

Carpenter, C. L., Kapur, K., Ramakrishna, P., Pamujula, S., Yadav, K., Giovanni, J. E., Julian, O., Ekstrand, M. L., Sinha, S., & Nyamathi, A. M. (2021). Lean Mass Improvement from Nutrition Education and Protein Supplementation among Rural Indian Women Living with HIV/AIDS: Results from Cluster Randomized Factorial Trial at 18-Month Follow-Up. *Nutrients*, *14*(1), 179. https://doi.org/10.3390/nu14010179

Chakrabarty, S., Islam, M., & Islam, A. (2017). Nutritional Benefits and Pharmaceutical Potentialities of Chili. *Fundamental and Applied Agriculture*, *2*(2), 272–232.

Challacombe, S. J. (2020). Global inequalities in HIV infection. *Oral Diseases*, *26*(S1), 16–21. https://doi.org/10.1111/odi.13386

Chen, X., Yu, B., & Zhao, L. (2019). The evaluation of global epidemic of HIV/AIDS with a novel approach using country-specific counts of HIV infections and three rates controlled for population and geographic area. *Journal of Global Health*, *3*(3), 66–67. https://doi.org/10.1016/j.glohj.2019.09.002

Chopra, H., Dey, P. S., Das, D., Bhattacharya, T., Shah, M., Mubin, S., Maishu, S. P., Akter, R., Rahman, M. H., Karthika, C., Murad, W., Qusty, N., Qusti, S., Alshammari, E. M., Batiha, G. E. S., Altalbawy, F. M. A., Albooq, M. I. M., & Alamri, B. M. (2021). Curcumin nanoparticles as promising therapeutic agents for drug targets. *Molecules*, *26*(16), 1–28. https://doi.org/10.3390/molecules26164998

Collin, S. M., Leclercq, B., Twungubumwe, N., Andréoletti, L., Richardier, F.-C., & Bertin, E. (2016). Leaf concentrate compared with skimmed milk as nutritional supplementation for HIV-infected children: A randomized controlled trial in Burundi. *Public Health Nutrition*, *19*(10), 1904–1912. https://doi.org/10.1017/S1368980015003456

Cooper, T. J., Woodward, B. L., Alom, S., & Harky, A. (2020). *Coronavirus disease 2019 (COVID-19) outcomes in HIV / AIDS patients: A systematic review*. 567–577. https://doi.org/10.1111/hiv.12911

Daka, D. W., & Ergiba, M. S. (2020). *Prevalence of malnutrition and associated factors among adult patients on antiretroviral therapy follow-up care in Jimma Medical*. *3*, 1–15. https://doi.org/10.1371/journal.pone.0229883

Daniela, E. V., Raúl, D. S. C., Carolina, B. H., Flor-Del-carmen, R. B., Sonia, L. G., Marcela, T. H., Irais, C. M., Luis-Benjamín, S. G., Mario-Alberto, R. G., Dealmy, D. G., & David, P. E. (2020). Adjuvant effect of garlic extracts (Allium sativum l.) on the production of γ globulin in mice immunized with ovalbumin. *Indian Journal of Traditional Knowledge*, *19*(2), 299–306.

Danwang, C., Noubiap, J. J., Robert, A., & Yombi, J. C. (2022). Outcomes of patients with HIV and COVID-19 co-infection: A systematic review and meta-analysis. *AIDS Research and Therapy*, *19*(1), 1–12. https://doi.org/10.1186/s12981-021-00427-y

Delshadi, R., Bahrami, A., McClements, D. J., Moore, M. D., & Williams, L. (2021). Development of nanoparticle-delivery systems for antiviral agents: A review. *Journal of Controlled Release*, *331*(January), 30–44. https://doi.org/10.1016/j.jconrel.2021.01.017

Dinçoğlu, A. H., & Yeşildemir, Ö. (2019). A Renewable Source as a Functional Food: Chia Seed. *Current Nutrition & Food Science*, *15*(4), 327–337. https://doi.org/10.2174/1573401314666180410142609

Dwivedi, G., Paul, V., & Bala, N. (2020). *Chia Seed: A good source of dietary fiber and nutrition*. *12*, 32–33.

Dwyer-Lindgren, L., Cork, M. A., Sligar, A., Steuben, K. M., Wilson, K. F., Provost, N. R., Mayala, B. K., VanderHeide, J. D., Collison, M. L., Hall, J. B., Biehl, M. H., Carter, A., Frank, T., Douwes-Schultz, D., Burstein, R., Casey, D. C., Deshpande, A., Earl, L., El Bcheraoui, C., … Hay, S. I. (2019). Mapping HIV prevalence in sub-Saharan Africa between 2000 and 2017. *Nature*, *570*(7760), 189–193. https://doi.org/10.1038/s41586-019-1200-9

Edelman, E. J., Aoun, L., Merceditas, B., & Gerald, V. (2020). Confronting Another Pandemic: Lessons from HIV can Inform Our COVID - 19 Response. *AIDS and Behavior*, 2–4. https://doi.org/10.1007/s10461-020-02908-z

Elfil, M., & Negida, A. (2017). Sampling methods in Clinical Research; an Educational Review. *Emergency*, *5*(1), e52.

Farhadian, M., Mohammadi, Y., & Mirzaei, M. (2021). Factors related to baseline CD4 cell counts in HIV / AIDS patients: Comparison of poisson , generalized poisson and negative binomial regression models. *BMC Research Notes*, 1–7. https://doi.org/10.1186/s13104-021-05523-w

Feng, Y. (n.d.). *The Lancet A Survey for COVID-19 among HIV / AIDS Patients in Two Districts of Wuhan, China A Survey for COVID-19 among HIV / AIDS Patients in Two Districts of Wuhan , China*.

Florindo, A. A., & Latorre, O. (2006). Central obesity and dietary intake in HIV / AIDS patients Obesidade abdominal e consumo alimentar em portadores de HIV. *Nutrition*, *40*(4), 634–640.

Folayan, M. O., Ibigbami, O., Brown, B., & Tantawi, M. E. (2022). Differences in COVID - 19 Preventive Behavior and Food Insecurity by HIV Status in Nigeria. *AIDS and Behavior*, *26*(3), 739–751. https://doi.org/10.1007/s10461-021-03433-3

François, L. M., Nagessa, W. B., Victor, B. M., Moleka, M., & Carvalho, I. S. T. D. (2020). Coronavirus and Nutrition: An Approach for Boosting Immune System-A Review. *European Journal of Nutrition & Food Safety*, *12*(9), 72–86. https://doi.org/10.9734/ejnfs/2020/v12i930285

Fulk, A., Romero-Alvarez, D., Abu-Saymeh, Q., Onge, J. M. S., Peterson, A. T., & Agusto, F. B. (2021). Using Google Health Trends to investigate COVID-19 incidence in Africa. *medRxiv*, 2021.03.26.21254369.

Gad, P., Gashema, I., Valens, P., Knowledge, M., & Tafadzwa, D. (2021). Knowledge, Attitude , and Practice Towards COVID - 19 Among People Living with HIV / AIDS in Kigali , Rwanda. *Journal of Community Health*, *46*(2), 245–250. https://doi.org/10.1007/s10900-020-00938-1

Gambo, A., Gqaleni, N., & Babalola, T. K. (2022). Dietary diversity and impact of Moringa oleifera Lam. leaves supplemented – Diet on the nutritional status and CD4 cell counts of patients receiving antiretroviral therapy in Nigeria: A double - Blind randomized trial. *Heliyon*, *8*(5), e09524. https://doi.org/10.1016/j.heliyon.2022.e09524

Gambo, A., Moodley, I., Babashani, M., Babalola, T. K., & Gqaleni, N. (2021). A double-blind, randomized controlled trial to examine the effect of Moringa oleifera leaf powder supplementation on the immune status and anthropometric parameters of adult HIV patients on antiretroviral therapy in a resource-limited setting. *PLOS ONE*, *16*(12), e0261935. https://doi.org/10.1371/journal.pone.0261935

Garnier, A., & Shahidi, F. (2021). Spices and herbs as immune enhancers and anti-inflammatory agents: A review. *Journal of Food Bioactives*, *14*, 20–52. https://doi.org/10.31665/jfb.2021.14266

Gebremedhin, K. B., & Haye, T. B. (2019). Factors Associated with Anemia among People Living with HIV/AIDS Taking ART in Ethiopia. *Advances in Hematology*, *2019*. https://doi.org/10.1155/2019/9614205

Gebreyesus, T., Belay, A., Berhe, G., & Haile, G. (2020). *Burden of fatigue among adults living with HIV / AIDS attending antiretroviral therapy in*. 1–10.

Germain, A. R. D. levine susan hanson maureen. (2017). 乳鼠心肌提取 HHS Public Access. *Physiology & Behavior*, *176*(3), 139–148. https://doi.org/10.1007/s10461-019-02645-y.Behavioral

Getaneh, Z., Wale, W., Chanie, B., Temesgen, E., Abebe, M., & Walie, M. (2021). Magnitude and associated factors of anemia among AZT based HAART experienced adult HIV patients at University of Gondar Comprehensive Specialized Referral Hospital, Northwest , Ethiopia , 2019: A retrospective cohort study. *BMC Infectious Diseases*, 1–12. https://doi.org/10.1186/s12879-021-06712-5

Girum, T., Wasie, A., Lentiro, K., Muktar, E., Shumbej, T., Difer, M., Shegaze, M., & Worku, A. (2018). Gender disparity in epidemiological trend of HIV/AIDS infection and treatment in Ethiopia. *Archives of Public Health*, *76*(1), 51. https://doi.org/10.1186/s13690-018-0299-8

González-Alcaide, G., Menchi-Elanzi, M., Nacarapa, E., & Ramos-Rincón, J. M. (2020). HIV/AIDS research in Africa and the Middle East: Participation and equity in North-South collaborations and relationships. *Globalization and Health*, *16*(1), 1–18. https://doi.org/10.1186/s12992-020-00609-9

Govender, R. D., Hashim, M. J., Khan, M. A., Mustafa, H., & Khan, G. (2021). Global Epidemiology of HIV/AIDS: A Resurgence in North America and Europe. *Journal of Epidemiology and Global Health*, *11*(3), 296–301. https://doi.org/10.2991/jegh.k.210621.001

Gupta, K. K., Attri, J. P., Singh, A., Kaur, H., & Kaur, G. (2016). Basic concepts for sample size calculation: Critical step for any clinical trials! *Saudi Journal of Anaesthesia*, *10*(3), 328–331. https://doi.org/10.4103/1658-354X.174918

Harding, B. N., Whitney, B. M., Nance, R. M., Ruderman, S. A., Crane, H. M., Burkholder, G., Moore, R. D., Mathews, W. C., Eron, J. J., Hunt, P. W., Volberding, P., Rodriguez, B., Mayer, K. H., Saag, M. S., Kitahata, M. M., Heckbert, S. R., & Delaney, J. A. C. (2020). *Anemia risk factors among people living with HIV across the United States in the current treatment era: A clinical cohort study*. 1–8.

Hong, H., Budhathoki, C., & Farley, J. E. (2018). Effectiveness of macronutrient supplementation on nutritional status and HIV/AIDS progression: A systematic review and meta-analysis. *Clinical Nutrition ESPEN*, *27*, 66–74. https://doi.org/10.1016/j.clnesp.2018.06.007

Jiang, H., Zhou, Y., & Tang, W. (2020). Maintaining HIV care during the COVID-19 pandemic. *The Lancet HIV*, *7*(5), e308–e309. https://doi.org/10.1016/S2352-3018(20)30105-3

Jiwani, S. I., Gillis, R. B., Besong, D., Almutairi, F., Erten, T., Kök, M. S., Harding, S. E., Paulsen, B. S., & Adams, G. G. (2020). Isolation and biophysical characterisation of bioactive polysaccharides from Cucurbita Moschata (Butternut squash). *Polymers*, *12*(8). https://doi.org/10.3390/POLYM12081650

Joshua, Z. P., Abarshi, M. M., Sani, I., Owolabi, O. A., David, M. A., Mada, S. B., Saliu, M. A., & Muhammad, A. (2021a). Impact of carrot-ginger blend on micronutrient status and CD4+ cell-counts of HIV-positive-patients on antiretroviral therapy in Kaduna, Nigeria. *Human Nutrition & Metabolism*, *26*, 200133. https://doi.org/10.1016/j.hnm.2021.200133

Joshua, Z. P., Abarshi, M. M., Sani, I., Owolabi, O. A., David, M. A., Mada, S. B., Saliu, M. A., & Muhammad, A. (2021b). Impact of carrot-ginger blend on micronutrient status and CD4+ cell-counts of HIV-positive-patients on antiretroviral therapy in Kaduna, Nigeria. *Human Nutrition & Metabolism*, *26*, 200133. https://doi.org/10.1016/j.hnm.2021.200133

Jumare, J., Ph, D., El-kamary, S. S., Magder, L., Ph, D., Hungerford, L., Ph, D., Umlauf, A., Franklin, D., Ph, D., Ghate, M., Ph, D., Abimiku, A., Ph, D., Charurat, M., Ph,

D., Letendre, S., Ellis, J., Ph, D., … Allen, J. (2020). *HHS Public Access*. *80*(2), 1–12. https://doi.org/10.1097/QAI.0000000000001906.Body

Kamwesiga, J., Mutabazi, V., Kayumba, J., Tayari, J.-C. K., Uwimbabazi, J. C., Batanage, G., Uwera, G., Baziruwiha, M., Ntizimira, C., Murebwayire, A., Haguma, J. P., Nyiransabimana, J., Nzabandora, J. B., Nzamwita, P., & Mukazayire, E. (2015). Effect of selenium supplementation on CD4+ T-cell recovery, viral suppression and morbidity of HIV-infected patients in Rwanda: A randomized controlled trial. *AIDS (London, England)*, *29*(9), 1045–1052. https://doi.org/10.1097/QAD.0000000000000673

Khatri, S., Amatya, A., & Shrestha, B. (2020). Nutritional status and the associated factors among people living with HIV: An evidence from cross-sectional survey in hospital based antiretroviral therapy site in Kathmandu, Nepal. *BMC Nutrition*, *6*(1), 1–13. https://doi.org/10.1186/s40795-020-00346-7

Kiptinness, E. M., & Kiwanuka-Tondo, J. (2019). The prevalence of HIV/AIDS frames in Kenya Newspapers: A summative content analysis of the Daily Nation. *Cogent Medicine*, *6*(1), 1596047. https://doi.org/10.1080/2331205x.2019.1596047

Kyle Burton, L. A. (2017). A Proposed Phase 1, Randomized Controlled Study to Determine whether a Combination of Ginger, Turmeric, and Sage Can Reduce C-Reactive Protein in Subjects Undergoing HIV Highly Active Anti-Retroviral Therapy. *8.5.2017*, הארץ.

Laila, U., Akram, M., Ali, M., Mehmmod, A., Naheed, H., Imtiaz, A., Tahir, M., Owais, A., Naveed, G., Muhammad, M., Naheed, R., Shaheen, G., Ullah, Q., & Zahid, R. (2019). *Role of medicinal plants in HIV / AIDS therapy*. *July*, 1063–1073. https://doi.org/10.1111/1440-1681.13151

Lancent, T. (2020). *Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID- research that is available on the COVID-19 resource centre—Including this Editorial Redefining vulnerability*. *January*.

Laurentiu Tatu, A., Mihaela Elisei, A., Lificiu, O., Diaconu, C., Miulescu, M., & Dumitriu Buzia, O. (2019). Formulation, preparation, physico-chemical, microbiological analysis and clinical uses of capsaicin microemulsions. *Revista de Chimie*, *70*(4), 1278–1282. https://doi.org/10.37358/rc.19.4.7109

Li, H. (2020). Evaluation of bioactivity of butternut squash (Cucurbita moschata D.) seeds and skin. *Food Science and Nutrition*, *8*(7), 3252–3261. https://doi.org/10.1002/fsn3.1602

Linda, D. (2018). *Nutritional Composition and Storage of Butternut Squash*. *12*(July), 1–23.

Liu, Y., Yao, J., Liu, X., Luo, B., & Zhao, X. (2018). A randomized interventional study to promote milk secretion during mother-baby separation based on the health belief model: A consort compliant. *Medicine*, *97*(42), e12921. https://doi.org/10.1097/MD.0000000000012921

Madala, N., & Nutakki, M. K. (2020). *Hot Pepper-History-Health and Dietary Benefits & Production*. *9*(4), 2532–2538.

Magadi, M., Gazimbi, M., Wafula, C., & Kaseje, M. (2021). Understanding ethnic variations in HIV prevalence in Kenya: The role of cultural practices. *Culture, Health and Sexuality*, *23*(6), 822–839. https://doi.org/10.1080/13691058.2020.1734661

Mahak Divya, Sanghi, Priya, Mishra, Divya, Puri, S. (2021). Traditional plants as immunobooster—Preventive strategy against COVID-19. *Bioved*, *30*(1), 153–166.

Marchionatti, A., & Parisi, M. M. (2021). *Anemia and thrombocytopenia in people living with HIV / AIDS : a narrative literature review*. *July 2020*, 98–109. https://doi.org/10.1093/inthealth/ihaa036

Matsumoto et al. 2017. (n.d.). Social Support as a Key Protective Factor against Depression in HIVInfected Patients: Report from large HIV clinics in Hanoi, Vietnam. *14/11/2017*.

Men, X., Choi, S. I., Han, X., Kwon, H. Y., Jang, G. W., Choi, Y. E., Park, S. M., & Lee, O. H. (2021). Physicochemical, nutritional and functional properties of Cucurbita moschata. *Food Science and Biotechnology*, *30*(2), 171–183. https://doi.org/10.1007/s10068-020-00835-2

Muna Ali, S. A. (2020). *The Effects of Moringa Leaves and Chia Seeds on Some Blood Parameters and Histopathology of Liver and Kidney to Boost Immunity of Diabetic Rats*. *36*, 149–166.

Muzembo, B. A., Ngatu, N. R., Januka, K., Huang, H.-L., Nattadech, C., Suzuki, T., Wada, K., & Ikeda, S. (2019). Selenium supplementation in HIV-infected individuals: A systematic review of randomized controlled trials. *Clinical Nutrition ESPEN*, *34*, 1–7. https://doi.org/10.1016/j.clnesp.2019.09.005

Nagarakanti, S. R., Bishburg, E., & Okoh, A. K. (2021). *Clinical outcomes of patients with COVID - 19 and HIV coinfection*. *19*(August 2020), 1687–1693. https://doi.org/10.1002/jmv.26533

Namdeo, P. (2021). *JPAR-2102-RSA-000196 Ms. Priyanka.pdf*. *4*(5), 1226–1237.

Nasimiyu, C., Matoke-muhia, D., Rono, G. K., Osoro, E., & Daniel, O. (2022). *Imported SARS-COV-2 Variants of Concern Drove Spread of Infections Across Kenya During the Second Year of the Pandemic*. 1–31.

National AIDS Control Council & National AIDS Control Council (NACC). (2018). Kenya HIV Estimates Report 2018. *Kenya HIV Estimates*, 1–28.

Nyagah, L. M., Young, P. W., Kim, A. A., Wamicwe, J., Kimani, M., Waruiru, W., Rogena, E., Oduor, J., Walong, E., Waruru, A., Oyugi, J., Downer, M., De Cock, K. M., & Sirengo, M. (2019). HIV-Related Deaths in Nairobi, Kenya: Results from a HIV Mortuary Surveillance Study, 2015. *Journal of Acquired Immune Deficiency Syndromes*, *81*(1), 18–23. https://doi.org/10.1097/QAI.0000000000001975

Nyamathi, A. M., Carpenter, C. L., Ekstrand, M. L., Yadav, K., Garfin, D. R., Muniz, L. C., Kelley, M., & Sinha, S. (2018). Randomized controlled trial of a community-based intervention on HIV and nutritional outcomes at 6 months among women living with HIV/AIDS in rural India. *AIDS (London, England)*, *32*(18), 2727–2737. https://doi.org/10.1097/QAD.0000000000002016

Nyamoita Mokua, G., Mokua Maroko, G., Onchari Nyakundi, A., & Ondora Onyambu, M. (2019). HIV/AIDS in Kisii County: Current Status and Challenges. *International Journal of HIV/AIDS Prevention, Education and Behavioural Science*, *5*(2), 147. https://doi.org/10.11648/j.ijhpebs.20190502.20

Omoruyi, B. E., Ighodaro, D. I., & Lewu, F. B. (2021). Analysis of some natural products for prevention of diseases associated with covid-19. *African Journal of Biomedical Research*, *24*(1), 11–23.

Pandey, A., & Galvani, A. P. (2019). The global burden of HIV and prospects for control. *The Lancet HIV*, *6*(12), e809–e811. https://doi.org/10.1016/S2352-3018(19)30230-9

Parise Adadi, & Kanwugu, O. N. (2020). *Living with HIV in the time of COVID - 19: A glimpse of hope*. 59–60. https://doi.org/10.1002/jmv.26118

Prinsloo, G., Marokane, C. K., & Street, R. A. (2018). Anti-HIV activity of southern African plants: Current developments, phytochemistry and future research. *Journal of Ethnopharmacology*, *210*(January 2017), 133–155. https://doi.org/10.1016/j.jep.2017.08.005

Rai, N., & Thapa, B. (2015). A study on purposive sampling method in research. *Kathmandu: Kathmandu School of Law*, *5*.

Rahman, M. M., Mosaddik, A., & Alam, A. K. (2021). Traditional foods with their constituent's antiviral and immune system modulating properties. *Heliyon*, *7*(1), e05957. https://doi.org/10.1016/j.heliyon.2021.e05957

Reddy, A. C. (2020). *Immunity: A Strong Defense against Corona Virus*. *9*(7), 127–137. https://doi.org/10.21275/SR20626184603

Rezaei, E., Sedigh Ebrahim-Saraie, H., Heidari, H., Ghane, P., Rezaei, K., Manochehri, J., Moghadami, M., Afsar-Kazerooni, P., Hassan Abadi, A. R., & Motamedifar, M. (2016). Impact of vitamin supplements on HAART related hematological abnormalities in HIV-infected patients. *Medical Journal of the Islamic Republic of Iran*, *30*, 350.

Rick, F., Odoke, W., & Avelino-, V. I. (2022). *Impact of coronavirus disease (COVID -19) on HIV testing and care provision across four continents*. *July 2021*, 169–177. https://doi.org/10.1111/hiv.13180

Ridgway, J. P., Schmitt, J., Friedman, E., Taylor, M., Devlin, S., Mcnulty, M., & Pitrak, D. (2020). NOTES FROM THE FIELD HIV Care Continuum and COVID - 19 Outcomes Among People Living with HIV During the COVID - 19 Pandemic, Chicago , IL. *AIDS and Behavior*, *Vl*, 8–10. https://doi.org/10.1007/s10461-020-02905-2

Rout, E., & Mohanty, J. N. (n.d.). *Differential expression of defense- related genes in chilli pepper infected with anthracnose pathogen Colletotric ...*

Rubavathi, S., Ayyappadasan, G., Sangeetha, N., Harini, T., Saranya, D., & Harshapradha, P. (2020). Studies on Antioxidant and Anti-Obesity Activity of Salvia hispanica (Chia) Seeds Extracts. *Journal of Drug Delivery and Therapeutics*, *10*(3-s), 98–106. https://doi.org/10.22270/jddt.v10i3-s.4169

Sabbah, A., Asero, R., & Senna, G. (2005). European Annals of Allergy and Clinical Immunology: Editorial. *European Annals of Allergy and Clinical Immunology*, *37*(2), 46.

Sahdeo Prasad, A. K. T. (n.d.). *Function*.

Saito, A., Karama, M., & Kamiya, Y. (2020). HIV infection, and overweight and hypertension: A cross-sectional study of HIV-infected adults in Western Kenya. *Tropical Medicine and Health*, *48*(1). https://doi.org/10.1186/s41182-020-00215-w

Scientific, R. (2020). *Research Article EDIBLE SEEDS AND NUTS IN HUMAN DIET FOR IMMUNITY DEVELOPMENT*. *11*, 38877–38881. https://doi.org/10.24327/IJRSR

Sharma, L. (2020). Immunomodulatory Effect and Supportive Role of Traditional Herbs, Spices and Nutrients in Management of COVID-19 *Dr Luxita Sharma. *Journal of PeerScientist*, *3*(2), 1–16. https://doi.org/10.20944/preprints202009.0026.v1

Shoko, C., & Chikobvu, D. (2019). *A superiority of viral load over CD4 cell count when predicting mortality in HIV patients on therapy*. *1*, 1–10.

Sieniawska, E., Maciejewska-Turska, M., Świątek, Ł., & Xiao, J. (2020). Plant-based Food Products for Antimycobacterial Therapy. *eFood*, *1*(3), 199. https://doi.org/10.2991/efood.k.200418.001

Silva, T. A. L., Medeiros, D. C., Medeiros, G. C. B. S., Medeiros, R. C. S. C., de Souza Araújo, J., Medeiros, J. A., Ururahy, M. A. G., Santos, R. V. T., Medeiros, R. M. V., Leite-Lais, L., & Dantas, P. M. S. (2019). Influence of curcumin supplementation on metabolic and lipid parameters of people living with HIV/AIDS: A randomized controlled trial. *BMC Complementary and Alternative Medicine*, *19*(1), 202. https://doi.org/10.1186/s12906-019-2620-7

Sorescu, A. A., Nuta, A., Ion, R. M., Radu, G. I., & Nistor, C. L. (2020). Phytosynthesis, kinetics and antioxidant activity of Waltham butternut squash aqueous extracts and metallic nanoparticles thereof. *Procedia Manufacturing*, *46*, 644–651. https://doi.org/10.1016/j.promfg.2020.03.092

Sorungbe, T., Jatau, B., Pharm, B., & Nedmbi, N. (2021). *Resource Setting*. *15*(January).

Sreshtaa, V. S., Leslie, S., & K, B. M. P. A. (2021). *Dietary Capsaicin and Immune System*. *25*(3), 5809–5822.

Suradkar, V. B., Wankhade, B. B., Patil, S. H., Narkhede, N. N., & Bhokare, I. D. (2017). Quantitative Determination of Some Phytochemical Contents of Various Plant Seeds and Leaves of Water, Ethanol and Methanol Extracts. *International Journal of Information Research and Review*, *04*(07), 4261–4264.

Sutliffe, J. T., Gardner, J. C., Gorman, M. M., Carnot, M. J., Wetzel, W. S., Fortin, T., Sutliffe, C. A., & Adams, A. (2019). Impact of a 6-Month Micronutrient-Dense Plant-Rich Nutrition Intervention on Health and Well-Being at the Worksite. *Journal of Nutrition and Metabolism*, *2019*, 2609516. https://doi.org/10.1155/2019/2609516

Teshale, A. B., & Tesema, G. A. (2022). Discriminatory attitude towards people living with HIV/AIDS and its associated factors among adult population in 15 sub-Saharan African nations. *PLoS ONE*, *17*(2 February), 1–14. https://doi.org/10.1371/journal.pone.0261978

Tesoriero, J. M., Swain, C. E., Pierce, J. L., Zamboni, L., Wu, M., Holtgrave, D. R., & Gonzalez, C. J. (2021). *COVID-19 Outcomes Among Persons Living with or Without Diagnosed HIV Infection in New York State*. *4*(2), 1–14. https://doi.org/10.1001/jamanetworkopen.2020.37069

Tshikuka, J. G., Magafu, M. G. M. D., Rankgoane-Pono, G., Mwita, J. C., Masupe, T., Hamda, S. G., Tapera, R., Molefi, M., Tshibangu, J., & Tlhakanelo, J. T. (2020). Overweight and Obesity among Recipients of Antiretroviral Therapy at HIV Clinics in Gaborone, Botswana: Factors Associated with Change in Body Mass Index. *AIDS Research and Treatment*, *2020*. https://doi.org/10.1155/2020/8016791

Tshingani, K., Donnen, P., Mukumbi, H., Duez, P., & Dramaix-Wilmet, M. (2017). Impact of Moringa oleifera lam. Leaf powder supplementation versus nutritional counseling on the body mass index and immune response of HIV patients on antiretroviral therapy: A single-blind randomized control trial. *BMC Complementary and Alternative Medicine*, *17*(1), 1–13. https://doi.org/10.1186/s12906-017-1920-z

Twinomujuni, S. S., Atukunda, E. C., Mukonzo, J. K., Nicholas, M., Roelofsen, F., & Ogwang, P. E. (2022). *Evaluation of the effect of Artemisia Annua L. and Moringa Oleifera Lam. on CD4 count and viral load among PLWH on HAART at Mbarara Regional Referral Hospital: A Double-Blind Randomized Controlled Clinical Trial*. http://ir.must.ac.ug/xmlui/handle/123456789/2748

Ullah, R., Nadeem, M., Khalique, A., Imran, M., Mehmood, S., Javid, A., & Hussain, J. (2016). Nutritional and therapeutic perspectives of Chia (Salvia hispanica L.): A review. *Journal of Food Science and Technology*, *53*(4), 1750–1758. https://doi.org/10.1007/s13197-015-1967-0

Uwishema, O., Taylor, C., Lawal, L., Hamiidah, N., Robert, I., Nasir, A., Chalhoub, E., Sun, J., Akin, B. T., Adanur, I., Mwazighe, R. M., & Onyeaka, H. (2022). The syndemic burden of HIV/AIDS in Africa amidst the COVID-19 pandemic. *Immunity, Inflammation and Disease*, *10*(1), 26–32. https://doi.org/10.1002/iid3.544

Virginia Melo-Ruíz, Beatriz Schettino-Bermúdez, Jesús Rodríguez-Diego, Rafael Díaz-García, Concepción Calvo-Carrillo, & CésarGazga-Urioste. (2016). Chia Seeds

(Salvia hispanica L) Wild Plant Rich in Nutrients. *Journal of Life Sciences*, *10*(5), 221–227. https://doi.org/10.17265/1934-7391/2016.05.001

Wang, D., Hou, X., Yu, X., Wang, T., Ye, Z., Li, J., Su, F., Guo, C., Peng, F., Zhao, S., Li, H., Zuo, J., Su, D., Zhao, L., Zhang, H., Chen, X., Wang, R., Xie, Q., Zheng, C., & Mao, G. (2021). Plasma hemoglobin and the risk of death in HIV/AIDS patients treated with antiretroviral therapy. *Aging*, *13*(9), 13061–13072. https://doi.org/10.18632/aging.202987

WHO. (2022). COVID-19 weekly epidemiological update. *World Health Organization*, *58*, 1–23.

Williams, A. M., Addo, O. Y., Grosse, S. D., Kassebaum, N. J., Rankin, Z., Ballesteros, K. E., Olsen, H. E., Sharma, A. J., Jefferds, M. E., & Mei, Z. (2019). *Data needed to respond appropriately to anemia when it is a public health problem*. *1450*, 268–280. https://doi.org/10.1111/nyas.14175

Wulantresna, D., Zuhrotun, A., & Chaerunisa, A. Y. (2021). Herbal Potential In Indonesia For Adjuvant Therapy To Corona Virus-19 Disease. *European Journal of Molecular & Clinical Medicine*, *7*(10), 1696–1707.

Xu, Y., Chen, X., Zhou, Z., Morano, J., Cook, R. L., Professions, H., Sciences, B., Carolina, N., & Medicine, I. (2021). *HHS Public Access*. *32*(7), 890–895. https://doi.org/10.1080/09540121.2019.1668521.

Xu, Y., Wang, X., Wang, F., Yang, J., & Wei, Y.-S. (2019). Epidemiological analyses of regional and age differences of HIV/AIDS prevalence in China, 2004-2016. *International Journal of Infectious Diseases: IJID: Official Publication of the International Society for Infectious Diseases*, *81*, 215–220. https://doi.org/10.1016/j.ijid.2019.02.016

Yang, X., Zhang, T., Su, B., Zhang, X., Liu, Y., & Wu, H. (2020). *Incomplete immune reconstitution in HIV / AIDS patients on antiretroviral therapy: Challenges of immunological non-responders*. *October 2019*, 597–612. https://doi.org/10.1002/JLB.4MR1019-189R

Yaseen, M. O., Jamshaid, H., Saif, A., & Hussain, T. (2021a). Immunomodulatory role and potential utility of various nutrients and dietary components in SARS-CoV-2 infection. *International Journal for Vitamin and Nutrition Research*, *1*, 1–14. https://doi.org/10.1024/0300-9831/a000715

Yaseen, M. O., Jamshaid, H., Saif, A., & Hussain, T. (2021b). Immunomodulatory role and potential utility of various nutrients and dietary components in SARS-CoV-2

infection. *International Journal for Vitamin and Nutrition Research*, *June*. https://doi.org/10.1024/0300-9831/a000715

Yaya, S., Bishwajit, G., Danhoundo, G., Shah, V., & Ekholuenetale, M. (2016). Trends and determinants of HIV/AIDS knowledge among women in Bangladesh. *BMC Public Health*, *16*(1), 812. https://doi.org/10.1186/s12889-016-3512-0

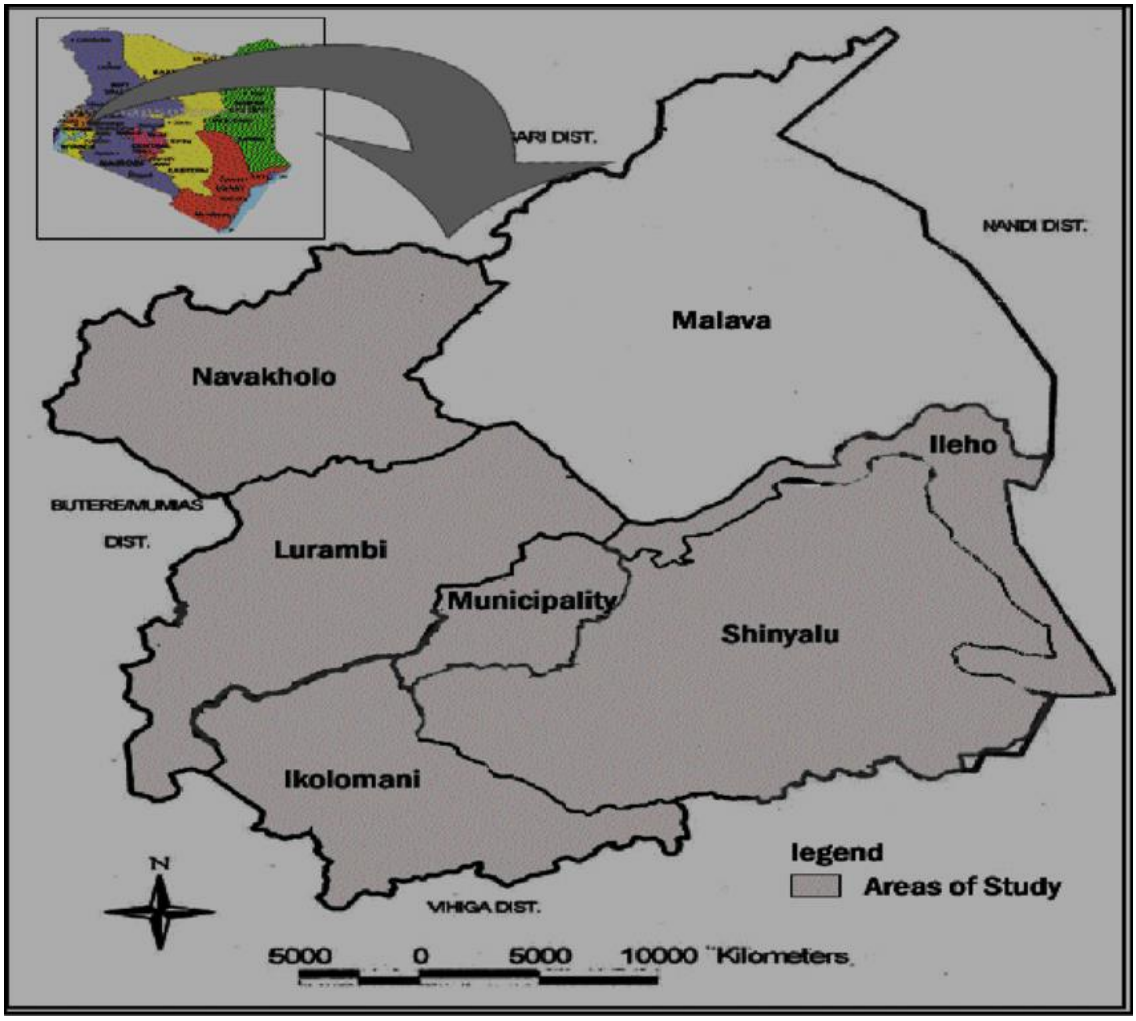
Yitbarek, G. Y., Engidaw, M. T., Ayele, B. A., Tiruneh, S. A., & Alamir, M. T. (2020). Magnitude of obesity/overweight and its associated factors among HIV/AIDS patients on antiretroviral therapy in Jimma Zone Hospitals, South West Ethiopia: Hospital-based cross-sectional study. *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy*, *13*, 1251–1258. https://doi.org/10.2147/DMSO.S247221

Yong Lu, D., Putta, S. A., Lu, D.-Y., Che, J.-Y., Sastry Yarla, N., Putta, S., Lin, L.-P., & Shen, Y. (2019). *Human Obesity, Pathological and Therapeutic Advances Cronicon EC PHARMACOLOGY AND TOXICOLOGY Review Article Human Obesity, Pathological and Therapeutic Advances*. *4*, 231–238.

Zerdali, E., Nakir, İ. Y., Sürme, S., Sayılı, U., & Yıldırım, M. (2021). *Predictors for tuberculosis co-infection in people living with HIV / AIDS*. *21*(3), 0–7.

APPENDICES

Appendix I: STUDY AREA MAP



A map of Kakamega County showing administrative divisions. Source: GoK (2002: 5)

APPENDIX II: MMUST DPS APPROVAL

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

20th January 2023

Antonette Nanjala Kivelenge
HMD/G/01-53689/2019,
P.O. Box 190-50100,
KAKAMEGA

Dear Ms. Kivelenge

RE: APPROVAL OF PROPOSAL

I am pleased to inform you that the Directorate of Postgraduate Studies has considered and approved your Masters Proposal entitled: "***Effects of Covi Soup on BMI, Immunological and Haematological Parameters among People Living with HIV in Kakamega County Kenya***" and appointed the following as supervisors

1. Dr. Jane Situma - MMUST
2. Dr. Lucy Mutuli - 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 Master's 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. Stephen O. Odebero, PhD, FIEEP
DIRECTOR, DIRECTORATE OF POSTGRADUATE STUDIES

Appendix III: MMUST ETHICAL APPROVAL

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 Scientific and Ethics Review Committee (ISERC)

REF: MMU/COR: 403012 Vol 6 (01)

Date: March 03rd, 2023

To: Antonette Nanjala Kivelenge

Dear Ms.,

RE: EFFECT OF COVI SOUP ON BMI, IMMUNOLOGICAL AND HAEMATOLOGICAL PARAMETERS AMONG PEOPLE LIVING WITH HIV IN KAKAMEGA COUNTY, KENYA.

This is to inform you that the ***Masinde Muliro University of Science and Technology Institutional Scientific and Ethics Review Committee (MMUST-ISERC)*** has reviewed and approved your above research proposal. Your application approval number is **MMUST/IERC/130/2023**. The approval covers for the period ***March 03rd, 2023*** to ***March 03rd, 2024***.

This approval is subject to compliance with the following requirements,

i. Only approved documents including informed consents, study instruments, MTA will be used
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***MMUST-ISERC***.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***MMUST-ISERC*** within 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to ***MMUST-ISERC*** within 72 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period Attach a comprehensive progress report to support the renewal
vii. Submission of an executive summary report within 90 days upon completion of the study to ***MMUST-ISERC***

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed

Yours Sincerely,

Prof. Gordon Nguka (PhD)
Chairperson, Institutional Scientific and Ethics Review Committee

Copy to:
- The Secretary, National Bio-Ethics Committee
- Vice Chancellor
- DVC (PR&I)

Appendix IV: PAN AFRICA CLINICAL TRIAL REGISTRY

11 July 2023

To Whom It May Concern:

RE: An Open Parallel Randomized Control Trial on Effect of COVI Soup on BMI, Immunological and Haematological Parameters Among People Living With HIV in Kakamega County Kenya

As project manager for the Pan African Clinical Trial Registry (pactr.samrc.ac.za) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR202307740330512**.

Please be advised that you are responsible for updating your trial, or for informing us of changes to your trial.

Additionally, please provide us with copies of your ethical clearance letters as we must have these on file (via email or post or by uploading online) at your earliest convenience if you have not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email pactradmin@mrc.ac.za should you have any questions.

Yours faithfully,

PACTR Admin
pactr.samrc.ac.za
+27 021 938 0835

The South African Medical Research Council
Cochrane South Africa | PO Box 19070, Tygerberg, 7505
Tel: +27 (0)21 938 0438 | Email: cochrane@mrc.co.za | Web: www.southafrica.cochrane.org

Appendix V: NACOSTI PERMIT

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: 143736

Date of Issue: 27/July/2023

RESEARCH LICENSE

This is to Certify that Ms.. Antonette Nanjala Kivelenge of Masinde Muliro University of Science and Technology, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Kakamega on the topic: Effect of Covi soup on BMI, Immunological and Hematological Parameters among People Living with HIV in Kakamega County Kenya for the period ending : 27/July/2024.

License No: **NACOSTI/P/23/28083**

143736

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.

See overleaf for conditions

Appendix VI: INFORMED CONSENT

Effect of Covi Soup on BMI, Immunological and Hematological Parameters Among People Living with HIV in Kakamega County, Kenya

I am a researcher from MMUST conducting a study on effect of Covi soup on BMI, immunological and hematological parameters among PLWH in Kakamega County Teaching and Referral Hospital. All your details are confidential and will be used for academic purpose. Recommendations from the study will be shared with the Ministry of Health to inform policies aimed at improving primary health care in the prevention and management of infections. For enquiries contact:

Antonette N. Kivelenge.

P.O BOX 150-50309, Kaimosi.

Email: kivelengeantonette@gmail.com

Mobile number: 0710136600

Autonomy

The researcher will allow the respondents to make a self-governed decision to participate in study.

Beneficence

The study findings will be used by different stakeholders for policy formulations.

Confidentiality

The names of the respondents will be delinked from the questionnaires and unique numbers assigned to conceal identity.

Informed Consent

Objectives of study will be clearly stated to allow respondents make informed decision to participate in the study through signing.

Justice

All the respondents will be treated with equality not considering; religion, age, gender, ethnicity, race or sociopolitical status.

Risks and benefits

The respondents will benefit from the nutritional counselling. Risks associated with the study such as food intolerance and allergies in which the respondents will be allowed to drop from study in case of any adverse effects.

(In case of any concern or problem, the respondent can contact the researcher through the cell phone contact 0710136600 or contact the department of Nutritional Sciences in MMUST)

I understand the objectives and details of this study and give my consent to participate in the study.

Yes…… NO……

Signature……. Date ……

Appendix VII: QUESTIONNAIRE

Identification Details

Date___ /____/ _____	Respondent number
Questionnaire identity number	Questionnaire checked by

Section A: Socio-demographic data *(Tick where appropriate)*

Gender	Male ☐ Female ☐
Age	(Years)
Year of Diagnosis/Duration with infection	(Years)
Occupation	Employed Retired Owns business Casual worker Farmer Any other (specify)
Residence	
Receipt of support	Yes ☐ No ☐

Section B: Anthropometric measurements

Body parameter	***Measurements***
Weight	(Kgs)
Height	(Cms)
BMI	(Kgs/M^2)

Section C: Food Frequency Questionnaire

How many times has the family/household eaten these foods in the last seven days?

Foods	***Frequency (1-7)***
Meats and meat products (fish)	
Breads/ Cereals/ Starch	
Poultry/ Egg	
Legumes / pulses	
Milk and milk products	
Fruits and vegetables	
Fats and oils	

Section D: Immunological and Hematological Parameters

Parameter	***Baseline***	***Post Study***
CD4+ cell count (cells/µL)		
VL		
Hb (g/dl)		
MCV		
MCH		
MCHC		

Section E: Type of Medication (*Tick Where Appropriate*)

Type of Medication	***Yes***	***No***
AZT + 3TC + NVP		
TDF + 3TC + LPV/r		
ABC + DDI + LPV/r		

Appendix VIII: LABORATORY REPORT FORM

LABORATORY

CD4 RESULTS—FACS PRESTO

Name : SEX: Spl No. : 5 SN:

Dept: IMMUNOLOGY Spl Type : BLOOD

Item Abb.	Test Results	Prompt Unit
CD4		cells/ul
%CD4		%
Hb		g/dL

TEST DONE BY: ' REVIEWED BY.:

Send Date: Test Date: Print Time: '

Appendix IX: A PACKET WITH SEVEN SERVINGS OF COVI SOUP