

FACTORS ASSOCIATED WITH WEIGHT GAIN AND BODY
MASS COMPOSITION OF MALNOURISHED HIV-
INFECTED ADULTS ON SUPPLEMENTS

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DECLARATION

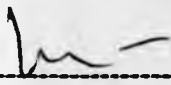
I hereby declare that this dissertation is my original work and has not been presented for a degree in any other University

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This thesis has been submitted for examination with my approval as a University supervisor

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Date 26/8/2011

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DEDICATION

To my mother Leonida Wandera, who has always inspired me to do my best.

To my husband Dr. T J Odula, my daughters Nadia and Zahra, for their never ending support and sacrifice.

And for you my understanding friends and family,who nudged me to go on when I was winded.

Declaration.....	I
Dedication.....	II
Table of contents	III
List of Tables.....	VII
List of Figures.....	VII
List of Appendices.....	IX
Acknowledgements.....	X
Abstract.....	XI

Table of Contents

1. INTRODUCTION.....	1
1.1 Background.....	1
1.2 Problem Statement.....	3
1.3 Justification.....	4
1.4 Study Objectives.....	5
1.4.1 General Objective.....	5
1. Specific Objectives.....	5
2. LITERATURE REVIEW.....	6
2.1 HIV Infection.....	6
2.2 Antiretroviral.....	7
2.2.1 Food–drug interactions.....	8

2.3 HIV and Nutrition.....	10
2.4 Body Composition and Wasting.....	13
2.4.1 Energy Metabolism.....	16
2.4.1.1 Resting Metabolic Rate.....	16
2.4.1.2 Energy Intake.....	17
2.4.2 Energy Malabsorption.....	18
2.4.3 Protein Metabolism.....	19
2.4.4 Loss of Body Protein.....	21
2.5 Investigational Methods for Determining Body Composition.....	23
2.5.1 Bioelectrical Impedance Analysis.....	23
2.5.2 Total body potassium.....	24
2.5.3 DEXA (Dual Energy X-ray Absorptiometry).....	24
2.5.4 Dilution methods	24
2.5.5 IVNAA (In-vivo Neutron Activation Analysis).....	25

3. STUDY SETTING AND METHODOLOGY.....	26
3.1 Study site.....	26
3.2 Study Design.....	27
3.3 Sample size determination.....	27
3.4 Sampling procedure.....	29
3.5 Research Instruments Used	31
3.6 Interventions.....	31
3.6.1 Food supplements.....	31
3.6.1 Follow-up Assessment.....	33
3.6.2 Nutritional Counselling.....	33
3.7 Data Collection.....	34
3.7.1. Socio-demographic data and baseline household parameters.....	34
3.7.2 Dietary consumption and Diversity.....	34
3.8 Ethical considerations.....	35
3.9 Recruitment and Training of Field Assistants.....	36
3.10 Data Quality Assurance.....	36
3.12 Data Analysis and Management.....	37

4.0 RESULTS.....	38
4.1 Background Characteristics.....	38
4.1.1 Socio demographic and economic status.....	38
4.2 Nutritional Status.....	47
4.2.1 Assessment of Nutritional Status.....	47
4.2.2 Dietary Diversity.....	48
4.2.3 Morbidity	51
4.3 Association with Other Variables.....	52
5. DISSCUSION.....	53
5.1 Socio Demographic profile.....	53
5.2 Nutritional Status	55
5.3 Morbidity.....	56
5.4 Association of socio-economic and demographic factors on change in BMI.....	57
6.0 CONCLUSION AND RECOMMENDATIONS.....	59
6.1 Conclusion.....	59
Recommendations.....	61
References.....	62

Appendices.....69

LIST OF TABLES

Table 1: Energy and nutrient density of Insta Foundation and DRI for PLWHA.....32

Table 2: Distribution of the study population by age and intervention group.....39

Table 3: Distribution of study population by age and gender.....40

Table 4: Distribution of study Population by Marital Status and gender.....41

Table 5: Distribution of study population by Education level and intervention.....41

Table 6: Distribution of study population by Education level and Gender.....42

Table 7: Main occupation by gender distribution of the study population.....43

Table 8: Amount Spent per Month for the Household Distribution by Gender.....44

Table 9: Income per Month for the household Distribution by Gender.....45

Table 10: Distribution of Study Population by Main Source of Food for the
Household and Gender.....46

Table 11: Means of body weight and composition.....47

Table 12: Distribution of study groups by food consumption.....48

Table 13: Distribution of the study group by the intevention and IDDS.....49

Table 14: Incidence of Illness Distribution of the Study Population by Intervention
Group in Percentages.....51

LIST OF FIGURES

Figure1:Conceptual model of the relationships among nutrients, food, health and drugs.....9

Figure2: Summary of the sampling procedure.....30

Figure 3: Distribution of study population by gender and intervention group.....38

Figure 4: Marital status of study population distribution.....40

Figure 5: Distribution of study population by main source of food for the household by intervention group.....45

Figure 6: Distribution of total study population by main source of food for the household.....46

APPENDICES

Appendix 1: Questionnaire.....69

Appendix 2: 24-Hour recall.....73

Appendix 3: Training schedule.....77

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ABSTRACT

Malnutrition is a frequent complication among HIV-infected persons and is associated with faster disease progression and mortality, and yet little has been documented on influence of food supplements on management of HIV/AIDS, in resource limited areas. A longitudinal study which employed descriptive and analytical methods of data collection and presentation was designed to assess the effect of dietary supplementation of HIV/AIDS patients on ARTs. A previously pre-tested structured questionnaire was used to interview a sample of 220 HIV/AIDS patients attending Maragua and Nyeri District hospitals. Data was collected on social demographic and socio-economic characteristics of the patients, dietary consumption and diversity, the anthropometry and morbidity of the patients.

The patients were randomly selected into two groups of 110 patients each. One group was given nutritional counselling and food supplements, while the other was given nutritional counselling only. Their nutritional status was recorded from baseline upto three months, using MUAC, BMI, body fat content and lean mass content. The data was collected and analysed for change.

The results showed that there was change in weight for 86.7% of the participants over a period of 3 months. Though there was no significant change in BMI, MUAC, body fat content and body lean mass between and within the intervention groups over the study period. There was also no significant association of change in MUAC, body fat content and body lean mass with the independent variables.

However BMI had significant association with money spent on food($p=0.018$) and main source of food for the household($p=0.041$). The main source of food showed a weak correlation($r=0.16$), while money spent on food indicated a negative correlation ($r=-0.20$) with change in BMI. There was also a weak correlation($r= 0.33$) between the two independent variables. The odds ratio analysis indicated that those who depend on farm produce are 1.8 times more likely to improve in weight than those who purchased their food.

The study was not able to establish that food supplements lead to increased weight gain and change in body composition within the study period. The Nutritional counselling alone effects increase in individual dietary diversity and food consumption. The nutritional counselling provided information that lead to change in the eating habits. At the same time, receiving food supplements had a negative influence on the consumption and diet diversity.

The study was able to establish that socio-economic and socio- demographic attributes can influence the nutritional status of PLWHA. The main source of food for the household significantly influenced the chances of improving the nutritional status of the participants. At the same time the percentage of the household budget used on food purchase influenced change in the nutritional status of individuals in that household. As the percentage increased there was decrease in the nutritional status.

CHAPTER ONE: INTRODUCTION

1.1 Background

Since the early 1980s, HIV/AIDS has claimed many lives and infected over 60 million persons, and it is likely to kill millions more before it is controlled. According to the Global Summary of the AIDS Epidemic(UNAIDS, 2008) there are 33.4 million people living with HIV worldwide , and the number is still growing. Its destruction is fuelled by a wide range of human rights violations, including sexual violence and coercion faced by women and girls, stigmatization of men who have sex with men, abuses against sex workers and injecting drug users, and violations of the right of young persons to information on HIV transmission. In prisons, HIV spreads with frightening efficiency due to sexual violence, lack of access to condoms, lack of harm reduction measures for drug users, and lack of information. Human rights violations only add to the stigmatization of persons at highest risk of infection and thus marginalize and drive underground those who need information, preventive services, and treatment most desperately.

Sub-Saharan Africa remains the region most heavily affected by HIV. In 2008, the Region accounted for 67% of HIV infections worldwide, 68% of new HIV infections among adults and 91% of new HIV infections among children. The region also accounted for 72% of the world's AIDS-related deaths in 2008(UNAIDS,2009). The epidemic continues to have an enormous impact on households, communities, businesses, public services and national economies in the Region.

In Kenya, HIV/AIDS is a national disaster. An estimated 1.4 million adults and children live with HIV/AIDS (Kenya Ministry of Health, 2009). And yet an estimated 83% of Kenyans living with HIV remained undiagnosed by 2007 (Kenya Ministry of Health, 2009). With a HIV prevalence rate of 6.1 % (UNAIDS, 2006), only about 70,000 Kenyans are receiving ART (WHO, 2006). UNAIDS estimates that about 140,000 persons died of AIDS in the country in 2005, compared to 2 million from the rest of the Sub Saharan Africa, and 2.8 million worldwide.

Evidence suggests that improved access to antiretroviral therapy is helping to effect a decline in HIV related mortality. This has been conclusively documented in high-income countries, where the beneficial effects of antiretroviral therapy are clearly apparent at the population level (Phillips et al., 2007). Similar evidence is starting to emerge from low- and middle-income countries. For example, in the first eight months of antiretroviral therapy scale-up in Northern Malawi, a population-level reduction in mortality of 35% was observed among adults (Jahn et al., 2008).

The recent improved coverage in treatment of opportunistic infections and use of antiretroviral therapy (ART) is expected to be accompanied by declined prevalence of wasting among HIV clients. Based on reports in developed countries (CDC, 1997) data from studies in the US indicate that wasting remains an important problem even in populations with widespread access to Highly Active Antiretroviral Therapy (HAART) (Wanke, Silva, Knox, et al, 2000).

There is still much uncertainty about the interactions between HIV/AIDS and malnutrition. Research suggests that the chance of infection with the HIV virus might

be reduced in individuals who have good nutritional status; the onset of disease and death might be delayed where HIV-positive individuals are well nourished; and diets rich in protein, energy and vitamins might reduce the risks of vertical transmission. Micro-nutrient deficiencies may increase the likelihood of mother-to-child transmission. Nutritional supplements, particularly antioxidant vitamins and minerals, may improve the immune function and other HIV-related outcomes, especially in nutritionally vulnerable populations.

1.2 Problem Statement

Increased treatment with potent ART may not improve nutritional status among AIDS patients. There are also suggestions that provision of energy dense foods are effective in increasing weight gain in PLWHA who are wasted or losing weight (Kotler, 2000). At the same time, other investigators maintain that increasing the caloric content alone of PLWHA does not satisfactorily induce weight gain, but weight gain would be improved in the presence of dietary supplements and caloric supplementation (Villarroya, 2001). However, while not ameliorating wasting, provision of food supplements to patients receiving ART did improve compliance with medication treatment regimens (Lo, MacGovern, Bradford, 2002). And yet, some nutrition experts have concluded food supplementation, is not likely to improve the weight of average patients on HAART (Marston and DeCock , 2004 and Mwamburi, et al., 2005).

Clinical studies to assess the role of food supplementation on reversing wasting have not been done in resource-constrained settings. In such settings, HIV patients would also face complications associated with the disease such as economic insecurity, social

isolation and stigmatization, inadequate cooking skills and facilities, limited food availability and dietary diversity, co-infections and other illnesses, and sometimes mental illnesses and disabilities. By the time many people with HIV get to the AIDS stage, all dimensions of food security—availability, stability, access and use of food—would be exaggerated. In such settings, both nutrition and other medical therapies would be needed to achieve medical management goals of AIDS patients (Grinspoon and Mulligan, 2003). High calorie diets may be required for patients with volume intolerances, barriers to adequate intake to restore and maintain nutritional status. Calories are required to restore lost weight or maintain weight, and additional protein may be required to improve body cell mass. All these show that studies on the effect of diet supplements are inconclusive and further studies are required.

1.3 Justification

A greater understanding of the flow of nutrients in HIV/AIDS will lead to more effective formulations of interventions for treating people with HIV/AIDS and malnutrition.

As many people who need treatment continue to lack access to ART despite significant ongoing scale-up of ART services, there is need for information on the potential impact of food supplementation on HIV/AIDS progression, especially on factors that are associated with weight gain and change in body composition. In addition, as Kenya scales up ART services, there is also a critical need for information about the impacts of appropriate food supplementation on the effectiveness of ART, on the health status of clients, and on the progression of the disease.

1.4 Study Objectives

1.4.1 General Objective:

To determine the factors associated with weight gain and the body mass composition among malnourished adults on ART and food supplements.

1.4.2 Specific Objectives:

- 1) Assessment of the socio-demographic and socio-economic characteristics of the HIV positive patients.**
- 2) Assessment of the nutritional status as MUAC, BMI and dietary diversity, and morbidity experience.**
- 3) To determine the weight gain and body mass composition of wasted HIV infected adults on ARV .**
- 4) Identify the factors associated with changes in weight gain and body mass composition of HIV positive patients on ART clients, receiving nutrition counselling and supplementary feeding.**

CHAPTER TWO: LITERATURE REVIEW

2.1 HIV Infection

HIV or Human Immunodeficiency Virus is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). HIV is a retrovirus that primarily infects vital components of the Human Immune System such as CD4+ T cells, macrophages and dendritic cells. It also directly and indirectly destroys CD4+ T cells. As CD4+ T cells are required for the proper functioning of the Immune System, when enough CD4+ cells have been destroyed by HIV, the immune system barely works, leading to AIDS. HIV directly attacks many organs, such as the kidneys, leading to acute renal failure, cardiomyopathy, dementia and encephalopathy affecting the heart and the brain. Many of the problems faced by people infected with HIV results from the failure of the immune system to protect them from opportunistic infections and cancers.

The life cycle of HIV can be as short as about 1.5 days: from viral entry into a cell; through replication, assembly, and release of additional viruses; to infection of other cells. HIV lacks proof reading enzymes to correct errors made when it converts its RNA into DNA via reverse transcription. Its short life cycle and high error rate cause the virus to mutate very rapidly, resulting in a high genetic variability of HIV. Most of the mutations either are inferior to the parent virus (often lacking the ability to reproduce at all) or convey no advantage, but some of them have a natural selection superiority to their parent and can enable them to slip past defenses such as the human immune system and antiretroviral drugs. The more active copies of the virus, the greater the possibility that one resistant to antiretroviral drugs will be made, so antiretroviral

combination therapy defends against resistance by suppressing HIV replication as much as possible.

HIV's actions and effects within the body, are multiple, numerous, synergistic, at best stressful and in the worst cases catastrophically tragic, painful and heart breaking (Elmore-Meegan, 2000). HIV primarily targets the immune system, favoring activated CD4+ immune cells, the gastro-intestinal tract, primarily the small and large intestines, being prime and rich reservoirs of these cells as well as being the sites of digestive and absorptive function. Herein lies a painful paradox, where the site and source of the body's sustenance, is also a prime target for infection and HIV transmission, consequent to the daily interactions and exchanges with the antigens introduced to the gut, HIV has a reservoir of potential cells to target (Schuttman et al, 1990; Veazey & Lackner, 1998). The target action of the HIV virus in the gastrointestinal tract initiates the deleterious effects on nutritional and immunological status in HIV+ individuals (Ullrich et al, 1989; Heise et al, 1991).

2.2 Antiretroviral Therapy

Antiretroviral drugs are medications for the treatment of infection by retroviruses, primarily HIV. Different classes of antiretroviral drugs act at different stages of the HIV life cycle. Combination of several (typically three or four) antiretroviral drugs is known as *Highly Active Anti-Retroviral Therapy (HAART)*.

There are several concerns about antiretroviral regimens. The drugs can have serious side effects (Saitoh et al 2005). Regimens can be complicated, requiring patients to take

several pills at various times during the day, although treatment regimens have been greatly simplified in recent years. If patients miss doses, drug resistance can develop (Dybul et al 2002).

If an HIV infection becomes resistant to standard HAART, there are limited options. One option is to take larger combinations of antiretroviral drugs, an approach known as *mega-HAART* or *salvage therapy*. Unfortunately, salvage therapy often increases the drugs' side-effects and treatment costs. Another is to take only one or two antiretroviral drugs, specifically ones that induce HIV mutations that diminish the virulence of the infection. The most common resistance mutation to the drug lamivudine (3TC), in particular appears to do this. Thus, 3TC can be somewhat effective even alone and when the virus is resistant to it.

2.2.1 Food–drug interactions

The efficient utilization of drugs and nutrients occurs through similar processes and it is therefore important to consider the potential interactions between nutrition and xenobiotics (defined here as substances foreign to the body, including ARVs). This is well illustrated in the diagram below.

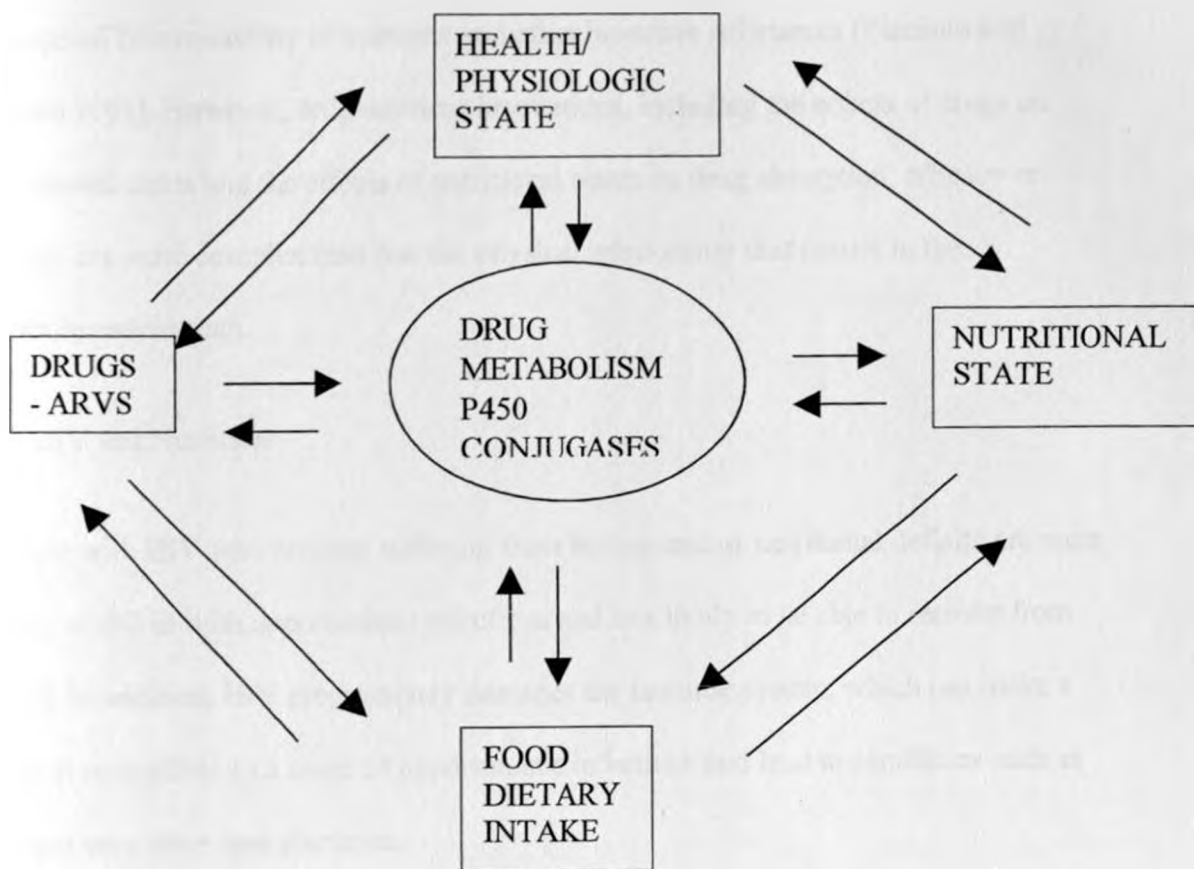


fig.1: Conceptual model of the relationships among nutrients, food, health and drugs.

Although consideration of the potential for food–drug interactions is most often limited to questions of bioavailability (i.e., specific physical interference of drug absorption due to the presence or absence of food or specific food components in the gastrointestinal tract), the metabolic fate of drugs, nutrients and other xenobiotics ultimately depends on nutritional factors. Interest has increased in the complexity of factors that affect all

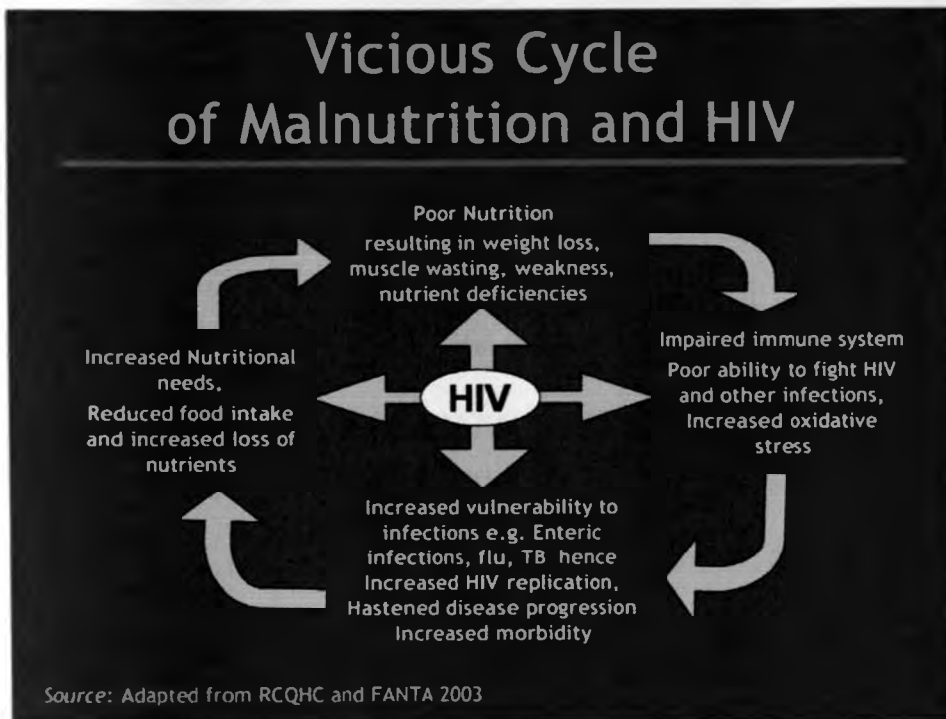
aspects of bioavailability of nutrients and other bioactive substances (Picciano and Raiten 2001). However, drug–nutrient interactions, including the effects of drugs on nutritional status and the effects of nutritional status on drug absorption, efficacy or safety, are more complex than just the physical relationship that occurs in the gastrointestinal tract.

2.3 HIV and Nutrition

People with HIV who are also suffering from hunger and/or nutritional deficits are more likely to fall ill with opportunistic infections and less likely to be able to recover from them. In addition, HIV progressively damages the immune system, which can make a person susceptible to a range of opportunistic infections and lead to conditions such as weight loss, fever and diarrhoea.

Infection affects nutritional status by increasing the utilization and excretion of protein and micronutrients as the body mounts its 'acute phase response' to invading pathogens. Infection also results in the release of pro-oxidant cytokines and other reactive oxygen species. This leads to the increased utilization of 'anti-oxidants' vitamins (e.g. Vitamin E, C, beta-carotene) as well as the sequestration of several minerals (e.g. Iron, Zinc, Selenium, manganese, Copper) that are used to form anti-oxidant enzymes (Friis and Michaelson, 1998). 'Oxidative stress' occurs when there is an imbalance between the pro-oxidants and anti-oxidants, causing further damage to cells, proteins, and enzymes (Schwartz, 1996).

These HIV-related conditions can lower food intake by reducing appetite and interfering with the body's ability to absorb food. HIV also alters metabolism, which can often lead to increased energy and nutrient requirements for people with HIV-infection.



As illustrated by the above diagram, malnutrition and HIV negatively affect each other. HIV infection may result in poor nutrition as a result of insufficient dietary intake, malabsorption, and altered metabolism.

This cycle has the following results:

- (a) Weight loss, the most common and often disturbing symptom of HIV, reported in 95 percent to 100 percent of all patients with highly developed disease

- (b) Loss of muscle tissue and body fat
- (c) Vitamin and mineral deficiencies
- (d) Reduced immune function and competence
- (e) Increased vulnerability to secondary infections
- (f) Increased nutritional needs because of reduced food intake and increased loss of nutrients leading to rapid HIV disease progression (FANTA, 2004)

Effective and economical ways to deal with the cycle of infection and poor nutrition include good nutrition, hygiene, and food safety. Early studies, which observed associations over time without providing specific nutrition interventions, showed that nutritional status and HIV were interrelated. These studies reported that weight loss was associated with HIV infection, disease progression, and shorter survival time (Piwoz and Preble 2000).

The benefit of food supplementation is still to be evaluated. While there have been a number of food supplementation programmes linked to HIV and AIDS, there has been no clear assessment of the biological benefits of these programmes to HIV-infected individuals. However, supplementary feeding may be beneficial in assisting compliance with ARV treatment, providing social support and encouraging PLWHA to access services more often.

Therapeutic feeding has been found to be effective in reversing moderate and acute malnutrition, but relapses are frequent once the patient returns to the environment that

led to the malnutrition. It is also extremely expensive. There is therefore a need to strengthen community coping mechanisms/safety nets.

2.4 Body Compositions and Wasting

One of the greatest fears of a person living with HIV/AIDS is having the "look" of a person with HIV-associated wasting. Loss of lean body mass and fat causes this skeletal appearance. Even in the era of HAART, HIV-associated wasting still occurs and has a significant effect on quality of life, illness and death.

The fact that wasting is not talked about much, not recognized or even monitored may be due to the focus placed on the body shape or metabolic (elevated blood fats, insulin resistance) changes occurring today. Wasting still occurs and to properly manage wasting, early detection and frequent monitoring is necessary.

According to Macallan(1993) in *Wasting HIV Infection and AIDS*, wasting may be either acute (associated with a secondary disease) or chronic (associated with gastrointestinal disease), and is the result of a variety of processes, including drug use, medications, concurrent disease, and HIV itself.

In order to accurately diagnose HIV-associated wasting, clinicians need to evaluate more than the total body weight of the patient. Total body weight may not change for years after a diagnosis of HIV infection. At the same time, however, body composition changes may be occurring even while the patient is asymptomatic. As lean body mass decreases, it is usually replaced by water and fat. After body cell mass reaches a value of 54% of normal, death ensues (Kotler et al 1989). It is particularly important to

remember that patients may show signs of wasting even when their body weight remains unchanged. As such, assessment of body cell mass is key to prevention, early intervention, and the monitoring of responses to treatment for HIV-associated wasting.

Factors that have been demonstrated or hypothesized to contribute to wasting include metabolic alterations, anorexia, malabsorptive disorders, hypogonadism, and excessive cytokine production. Because wasting in most cases results from a combination of factors or failed compensatory responses, the diagnostic process must recognize the possibility of multiple etiologies.

Increased resting energy expenditure (REE) is a common finding in patients with HIV infection, (Grunfeld et al 1992) especially in those with systemic secondary infections (Melchior et al 1993).

A variety of other metabolic changes have also been described in HIV-infected individuals, including: increased (Macallan et al 1995) and decreased (Stein et al 1990) rates of protein turnover; decreased rates of muscle protein synthesis (Yarasheski et al 1998); and increased rates of de novo hepatic lipogenesis, (Hellerstein et al 1993) lipid flux, and oxidative and non-oxidative lipid disposal(Mulligan et al, 1993). As of yet, no mechanistic relationship has been demonstrated between these or other metabolic alterations and wasting. In fact, it has been shown that the reversal of wasting is not contingent upon a reversal of elevated REE(Mulligan et al 1998).

As discussed above, decreased energy intake, coupled with inappropriately elevated REE, is a major factor in negative energy balance that results in weight loss. Anorexia

can result from a variety of factors caused by HIV infection itself, secondary infection, and treatments for either. Painful oral and esophageal complications such as candidiasis and aphthous ulcers can reduce voluntary food intake. Nausea is a frequent adverse effect of medications. Depression, fatigue, altered taste perception, and social isolation can also contribute to anorexia or loss of interest in eating. Moreover, dosing regimens for some antiretroviral medications impose restrictions on feeding schedules that can limit the opportunities for eating.

Impotence and low testosterone levels have been reported in men with AIDS, even in the absence of weight loss(Croxson et al 1989). Decreased testosterone levels may be the result of a functional disorder of the hypothalamus(Dobs et al, 1988), primary testicular failure(Croxson et al, 1989), or both. HIV-infected men with wasting have been reported to have significantly lower total and free testosterone levels than weight-stable men(Coodley et al, 1994). In hypogonadal men with wasting, muscle mass and total body potassium (an index of body cell mass) were found to be positively and significantly correlated with serum free testosterone levels, and exercise capacity correlated with total testosterone levels(Grinspoon et al, 1996). It is not yet clear whether decreased testosterone levels are a cause or consequence of wasting. Decreased free testosterone levels have also been found in HIV-infected women with wasting (Grinspoon et al, 1997).

Chronic diarrhea and malabsorption remain common findings in HIV-infected patients. Where ART is available, diarrhoea associated with intestinal pathogens such as microsporidia, *Cryptosporidium*, *Giardia lamblia*, cytomegalovirus (CMV), and

Mycobacterium avium has decreased, whereas ART-associated diarrhoea has increased. Thus, the overall incidence rate of diarrhea has remained constant (Callet al, 2000). In addition to a loss of calories associated with malabsorption, diarrhoea can secondarily contribute to weight loss by discouraging food intake. The quantitative contribution of diarrhoea and malabsorption to wasting has not been described.

2.4.1 Energy Metabolism

2.4.1.1 Resting Metabolic Rate

As with many infections increased resting metabolic rate (RMR) is often suggested as an important factor for energy imbalance in HIV/AIDS. There are differences in energy expenditure between children and adults with HIV/AIDS. Most studies in adult patients show that RMR is around 10% higher than in control groups. RMR is highest in those with the most severe disease. In particular those with secondary infection had higher RMRs than did patients without secondary infection. Unlike adults, most studies in children show no difference in RMR between infected and uninfected children, though studies do show raised energy expenditure in children with opportunistic infections. The different results in children and adults may be due to differences in nutritional status, dietary intake or disease severity. It is important to recognize that the effects of energy imbalance is more serious in children than adults because a high proportion of energy is required for growth in healthy children and for catch up growth by children recovering from an opportunistic infection. Thus, despite the generally consistent finding that RMR is increased by 10% among adults with HIV/AIDS, change in RMR alone does not account for weight loss in adults and hardly contributes to weight loss in children. Other

factors that contribute to total daily energy expenditure (TDEE) include physical activity, growth and diet-induced thermogenesis; these are not taken into account in measurement of RMR. Variations in results of measurements of energy expenditure are likely due to differences in dietary intake, nutritional status, physical activity, and severity of opportunistic infection. However overall RMR is increased by about 10% in HIV/AIDS and is especially high during acute severe episodes of opportunistic infection.

2.4.1.2 Energy intake

Loss of appetite leading to reduced energy intake is the main reason why people lose weight in HIV/AIDS. Reduction in dietary intake leads to growth failure in HIV-positive children and wasting in HIV-positive adults (Macallan DC.1999.). Poor dietary intake is due to the metabolic processes, which reduce appetite in many infections (Powanda MC, Beisel WR. 2003).

Both systemic infections such as TB and intestinal infections including *Cryptosporidium* and oesophageal candidiasis are especially important. Poor dietary intake as a result of severe underlying infection may account for slow rates of recovery among children with severe malnutrition. Certain anti-retroviral drugs (ARVS) may cause Anorexia and conversely as patients with HIV/AIDS start to improve clinically once they get established on ARVs, they can develop a voracious appetite. Unless food is available the benefits of ARVs are not achieved. Overall anorexia leading to a reduced nutrient intake is the most important cause of weight loss in HIV-positive patients. Encouraging severely malnourished children to eat is often difficult until their

infections are adequately treated. This is especially so if severely malnourished children are infected with HIV/AIDS; encouraging children to eat when they have HIV/AIDS associated diarrhoea is a major challenge . Among many patients with HIV/AIDS, poor dietary intake occurs in a background of poverty and lack of food in the household. Things may get even worse because HIV/AIDS prevents people from feeling well enough to work - either to grow enough or to earn enough to buy food. Poor environmental conditions – especially contaminated water supplies and crowded living conditions, especially where TB and pneumocystis are rife, lead to frequent opportunities for colonisation by opportunistic infections that cause local pain and ulceration in the mouth, which together with fever and breathlessness lead to further reduction in appetite even when there is urgent need to replenish body nutrient stores. The complexities of metabolic responses in infection and their impact on appetite and body nutrient stores are discussed in detail during studies in other infections .

2.4.2 Energy Malabsorption

Intestinal malabsorption leading to nutrient energy loss is common in patients with HIV/AIDS. Chronic weight loss in HIV/AIDS is often related to gastrointestinal disease and malabsorption. In addition to the damage to the intestinal villi caused by HIV, *Cryptosporidium*, one of the commoner and more serious opportunistic gut infections, for example, causes malabsorption and the degree of intestinal injury is related to the number of organisms infecting the intestine. Several studies have shown that those with more severe malabsorption have lower body mass index. Possible mechanisms responsible for malabsorption in HIV/AIDS include the impact of HIV on villi, specific

enzyme deficiencies in intestinal mucosa, the effect of opportunistic infections and altered intestinal transit have all been considered but these are mainly conjectural and effective treatments remain to be developed. High levels of faecal fat occur; one study showed that over 90% of HIV-positive patients had high faecal fat levels that were not related to dietary fat intake (Poles et al, 2001). Over 80% of HIV-positive patients in one study had faecal fat levels in the range of 20–30% of dietary fat intake. With these high levels of fat malabsorption, a negative energy balance will develop unless there is considerable increase in dietary energy. Malabsorption of iron also occurs .

2.4.3 Protein Metabolism

2.4.3.1 Protein intake

Protein deficiency is closely associated with energy deficiency; both are often deficient in HIV/AIDS and there is evidence of severe protein deficiency in HIV/AIDS that has been proposed that children and adults with HIV/AIDS need much more protein than in their uninfected peer. Establishing the amount of protein, which an individual needs to maintain body composition and function, and, in the case of children, to grow is difficult. . Most studies have examined the metabolism of individual labeled amino acids, as they become incorporated into pools of body protein or excreted as metabolic products. Thus a key question is frequently asked: Do HIV-positive individuals need to eat more protein or a different proportion of protein in their diet? A clinical state of protein depletion suggests that greater amounts of dietary protein are required. However much evidence from animal and human studies models in septic or catabolic states similar to HIV/AIDS shows that increased levels of amino acid or protein intake are not

utilized adequately . Several pro-inflammatory cytokines are produced during infection, which results in poor appetite and failure to grow or regain lost weight even when abundant nutrient supplies are provided . There are informative examples of abnormal protein metabolism in infected children and adults (Morlese et al, 1998). Several of these have involved providing considerable amounts of protein. Increasing dietary intake certainly changes protein metabolism and the balance between anabolism and catabolism but it does not appear that overall additional protein intake can replace lost protein stores until the infection is better managed. Thus, provision of additional protein does not in any way guarantee increased lean body mass and recovery of blood protein levels. Although weight gain often occurs in HIV-positive patients with active opportunistic infection who are treated with total parenteral nutrition, body composition analysis showed that the weight gained was predominantly fat (Kotler et al, 1999).

Administration of excess dietary amino acids requires disposal processes including deamination and oxidation; these processes themselves require energy. Direct evidence for specific clinical benefit from known increments of protein intake is largely lacking and will depend on the nutritional and inflammatory state of the patient. Dietary protein intake is often reduced in HIV/AIDS, especially during opportunistic infection; it is difficult to overcome this dietary reduction and doing so in the presence of opportunistic infection can be harmful.

2.43.2 Loss of body protein

Body protein loss is due to poor dietary intake, malabsorption and metabolic change. In the absence of adequate energy intake, body fat and protein are used as fuel sources, thus energy and protein metabolism cannot be separated within the context of clinical HIV/AIDS. During weight loss in HIV/AIDS the proportion of body stores that are lost, be they protein, fat or carbohydrate depends on the underlying nutritional state and the dietary intake. The proportion of loss of each compartment varies between individuals, possibly a result of genetic differences.

Fat is usually lost first and as body fat stores become progressively depleted, more lean body mass is lost per kilogram of total weight loss. The overall result is that protein depletion becomes more striking once fat reserves are lost. These changes are widely described in many wasting illnesses, but HIV seems to induce a special metabolic effect in the host involving a preferential loss of protein over fat . Evidence for preferential protein depletion in HIV comes largely from many cross-sectional body composition studies in which patients with AIDS wasting have been found to have proportionately greater loss of lean mass than fat (Kotler 2000). All studies do not support this hypothesis, however. In a longitudinal study of weight and body composition in HIV patients, the ratio of change in lean body mass to total body weight was similar to that found in dietary deprivation alone .

Patients with HIV/AIDS experience frequent episodes of clinical infection from repeated opportunistic pathogens infections, in between which they can rebuild nutrient stores. Repeated episodes of weight loss due to loss of fat and lean tissue followed by

recovery appear to allow fat to be preferentially repleted and thus measurement of weight gain without assessment of body composition may lull clinician into a false sense of security. Indeed preferential fat repletion occurs elsewhere – in post starvation refeeding , in TB .Whatever the metabolic mechanisms responsible for change in body composition in HIV/AIDS, they may be different from those present in chronic food insufficiency or loss of weight due to cancer. Loss of protein mass is markedly accelerated during opportunistic infections.

Endocrine changes have been noted in chronic dietary deficiency and certain infections but their contribution to metabolism and changes in body composition seem particularly striking in HIV/AIDS. Gonadal function is altered in HIV infection and hypotestosteronaemia may result in substantial loss of muscle mass . Screening for hypogonadism as part of the clinical assessment of HIV-infected subjects provides the potential for endocrine treatment as a means of enhancing lean body mass; this is discussed below. Loss of body protein during HIV/AIDS is therefore caused by poor diet, malabsorption, endogenous intestinal losses and altered metabolism; all are more striking during opportunistic infection.

There is no reason to expect that the intimate relationships between nutrition and drug metabolism should be different in PLWHA than in uninfected populations. What is not known are the specifics of the association among the natural history of HIV infection, consequent effect on the full range of nutrition processes, and pharmacology of ARVs on weight gain and body cell composition. What has emerged from the limited number of studies is that a real potential exists for these interactions and that PLWHA need to

receive appropriate counseling to ensure safe and efficacious delivery of ARVs (Daniel et al, 2005)

2.5 Methods for Determining Body Composition

2.5.1 Bioelectrical Impedance Analysis

Bioelectrical impedance analysis (BIA) is the preferred method for assessing body cell mass depletion, even in the presence of normal weight (Muurahainen et al., 1994). BIA can be easily performed with portable equipment in the office setting, involves no radiation, is inexpensive, painless, and has a high degree of accuracy. A low-level current of 800 micro amps is introduced into the patient, and voltage changes are recorded via electrodes attached to their hands and feet. Lean tissue contains most of the body's conducting electrolytes, and therefore, conducts electric current more readily than fat tissue, which has lower water content. The numerical results of BIA are combined with the patient's other statistics (height, weight, sex, and age) to calculate body cell mass, fat-free mass, and other body composition measurements.

Body cell mass consists of metabolically active tissue, which includes muscle tissue, organ tissue, and intracellular water (Roubenoff and Kehayias, 1991) Body cell mass is a component of lean body mass, which also includes extra cellular water and bone tissue. Therefore, it is important to remember that lean body mass contains more than just muscle.

BIA is the most accessible, reliable, efficient and accurate test for measuring body cell mass. Not all BIA machines use the same software. Differences among machines and

methodologies can result in calculations that can vary by as much as 10%. BIA results may also be affected by the patient's level of hydration. As such, BIA is much less reliable for measuring fat mass. BIA is most effective as an ongoing assessment tool to longitudinally measure changes in body composition. (National Institutes of Health, 1994).

2.5.2 Total body potassium

Fat is potassium-free and bones contain only traces of potassium. For this reason, practically the entire content of potassium in the body (98%) is to be found in the cells of the BCM. The natural radioactive isotope K40 is present wherever potassium is found at a level of 0.012%. By measuring the isotope K40 it is possible to draw conclusions about total body potassium and thus the BCM. The measurement of K40 is done in a whole body counting chamber.

2.5.3. DEXA (Dual Energy X-ray Absorptiometry)

DEXA is carried out using a special x-ray apparatus at a very low radiation dosage. Two beams of photon radiation with different energy levels are used, which gives the method its name. DEXA can be used to differentiate between bone mass, fat mass and fat-free mass.

2.5.4 Dilution methods

The dilution techniques are used mostly to determine total body water TBW. Deuterated water is used as a non-radioactive tracer; it can be given orally or parenterally. About 2

hours after the dose, the concentration of the tracer is determined in the urine and blood using gas chromatography or mass spectrometry, allowing a conclusion to be drawn about the total body water. The extra-cellular fluid can be determined selectively using bromide or sulphate.

2.5.5. In-vivo Neutron Activation Analysis (IVNAA)

This is probably the most expensive of all methods for determining the body composition; but it also provides the most differentiated assessment. A beam of neutrons aimed at the body induces the emission of gamma radiation with a characteristic spectrum. In this way, single elements can be determined, such as total body potassium or calcium. The corresponding compartment can be calculated from the proportion of these elements. Further imaging processes for determining the composition of the body are mentioned below:

Nuclear magnetic resonance technique (NMR)

Computer tomography (CT)

Magnet resonance tomography (MRT)

Photon absorption measurement

CHAPTER THREE: STUDY SETTING AND RESERCH METHODOLOGY

3.1 Study Site

This study was carried out in Maragwa and Nyeri District hospitals. Maragwa District hospital is a public facility situated about 65km and Nyeri Distret hospital is 120km North West of Nairobi. The two hospitals are located in areas with similar topographical characteristics. The hospitals had a client base of 1210 of whom 500 were on ART. In the last three months before the study they recruited about 30 new ART clients per month. The hospitals were able to recruit about 120 ART clients and 200 pre-ART clients in a quarter, of which 70% were estimated to have a BMI<18.5. From these sites, the study estimated that it would be able to recruit about 250 ART clients over a period of 4 months.

Eligible subjects were HIV-infected adults (> 18 years old) who were scheduled to begin treatment with ART within five weeks and who had a body mass index (BMI) of less than 18.5. Women who were pregnant or lactating were excluded, as well as women who later became pregnant during the period of the study. The study group was made of wasted adult clients eligible for ART, according to WHO guideline (WHO, 2003) and Kenya national ART guidelines (NAS COP, 2002).

The eligible patients were randomly divided into two groups. One group received nutritional counselling alone, while the other received food supplementation in addition to the nutritional counselling . Baseline socio-demographic and socio-economic,

nutritional, and morbidity data were collected using questionnaires. And a 3-months follow-up on nutritional and morbidity data were collected.

3.2 Study Design

This study was a longitudinal study designed to establish the effects of supplementary feeding on weight gain of malnourished HIV patients on ARV therapy. The study involved both descriptive and analytical methods of data collection and presentation.

The study was part of a major study by the Kenya Medical Research Institute (KEMRI) working with Insta Products Ltd. and AED/FANTA to conduct the operations of the research. Two basic groups of clients were considered for the evaluation. HIV-infected adults for the study were recruited from patients attending comprehensive care clinics (CCC) and enrolled for administration of ART and those referred from Voluntary Counselling and Testing Centres (VCT).

3.3 Sample size determination

The primary outcome of the study was the improvement in nutritional status measured using BMI after 3 months of follow-up. Using the formula below, the sample size needed to detect differences in BMI of 0.5, with 95% level of confidence and 90% power of test. Going by an average expected BMI increase of 0.5 kg/m², with an assumed standard deviation of 1.77 kg/m².

The following formula was used for sample size computation: -

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 2\sigma^2}{(\mu_1 - \mu_2)^2}$$

Where:

Z = The Z-value attributed to α and to 1-b.

1-b. = The power of the study (90%)

α = significant level (at 0.05)

$\mu_1 - \mu_2$ = the expected difference (nutrition counseling and supplementation) in BMI that can be detected by sample to claim effect of supplementation =0.5

That is:

$$\frac{(1.96+0.84)^2 2(1.77)^2}{(0.5)^2} = 196$$

The sample size required to detect such a difference is 196.

Assuming a 12% attrition a sample of 220 wasted HIV positive patients was recruited into the study.

Inclusion criteria

1. Wasted HIV positive patients (BMI < 18.5) on ARV treatment started within 1 month
2. Resident within the area for at least 6 months and not likely to move out.

Exclusion criteria

1. HIV positive patients with BMI ≥ 18.5 kg/metre²
2. All pregnant and lactating women
3. Any patients previously on ARVs

3.4 Sampling procedure

The study proposed to utilise a complete random design in the allocation of subjects to various treatment intervention. Then 220 clients were recruited and randomisation was done to allocate the patients to either treatment intervention within each block.

A random numbered assignment of numbers was generated and each patient was required to collect a card number, which was matched to either of the two treatments that were available in opaque sealed envelope, which were given to the subject upon completing the informed consent process. The subject was presented the card for food collection, at an adjacent room/site adjacent to the clinic, where nutritional counselling was offered to all for healthy eating with HIV and food supplements. This procedure was applied for both sites independently to acquire the total sample size.

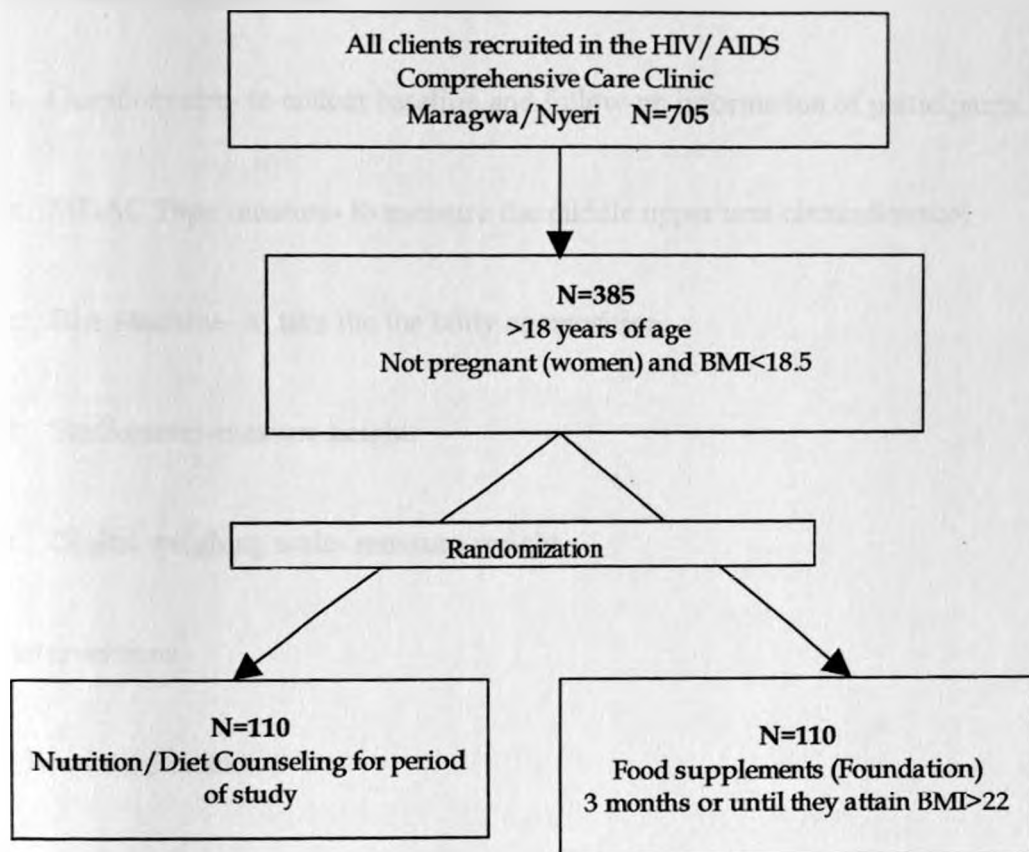


Figure2: Summary of the sampling procedure

3.5 Research instruments used

- a. Questionnaire- to collect baseline and follow-up information of participants.
- b. MUAC Tape measure- to measure the middle upper arm circumference.
- c. BIA Machine- to take the the body composition.
- d. Stadiometer-measure height.
- e. Digital weighing scale- measure weight.

3.6 Interventions

3.6.1 Food supplements

The food supplement used in this study was produced by Insta Foods Kenya ltd, based at the Export Processing Zone (EPZ) in Athi River. The product, known as Insta Foundation, is a blend of maize, soya, sugar, palm oil, and micronutrients pre-mix. The content of energy and nutrients is shown in the table below and has been confirmed by SGC International. The supplement provided about a third of the daily energy requirement of the patients.

Table 1: Energy and Nutrient Density of Insta Foundation and Daily Ration Intake(DRI) for PLWHA

Nutrient	Insta 300g/day	DRI Woman (HIV+)	DRI Man (HIV+)
Energy (kcal d-1)	1360	3022	3022
Protein (g.d-1)	50	46	56
Calcium (mg.d-1)	258	1000	1000
Phosphorus (mg.d-1)	1050	700	700
Magnesium (mg.d-1)	500	310	400
Potassium (mg.d-1)	1700	4700	4700
Selenium (ug.d-1)	22	55	55
Zinc (mg.d-1)	8	8	11
Copper (mg.d-1)	2.9	0.9	0.9
Iron (mg.d-1)	16	18	8
Vitamin A (ug.d-1)	340	700	700
Vitamin C (mg.d-1)	26	75	90
Vitamin D (ug.d-1)	6	5	5
Vitamin E (mg.d-1)	32.5	15	15
Niacin (mg.d-1)	13	14	18
Folic Acid (ug.d-1)	153	400	400
Thiamine (mg.d-1)	1.3	1.1	1.2
Riboflavin (mg.d-1)	0.8	1.1	1.3
Vitamin B6 (mg.d-1)	1	1.3	1.3
Vitamin B12 (ug.d-1)	0.5	2.4	2.4

DRI values taken from the Institute of Medicine for adults 19-30 years for non pregnant and non lactating. * *Energy requirement values based on calc. made by KEMRI (HIV-symptomatic individuals)*

Insta Foundation was a pre-cooked product and only needed reconstitution using boiling hot water for consumption. The food was packed in 3 packets of 100g each, or total of 300g, the targeted supply for a day. Each patient was provided with a months' supply, which was 10kg (300g x 30=9000g + additional buffer supply for three days). The food was labelled with instructions on how to prepare it, the nutrient content, and had space on the label for the name of the client and a return date. Each client was instructed on how to use the food and given strict instructions not to share the food with others whether within or outside the household.

3.6.2 Follow-up Assessment

The food supplement was distributed monthly at the nutrition centres within the study sites where nutritional counselling was available for all referred clients. Follow-up assessment on adherence on use of the food was conducted during clients' monthly visits to the treatment centre. In cases of drop-outs, efforts were made through home visits and other approaches to determine whether death was the reason for drop-out.

3.6.3 Nutritional Counselling

All patients in the study received nutritional counselling which was carried out by a trained nutritionist/dietician attached to the CCC and involved supporting the client on weight management, and in management of dietary related symptoms. Food demonstrations were also done in the process of counselling.

3.7 Data Collection

Staff specifically trained as enumerators undertook all data collection. To avoid duplication of information being collected for the study and information collected in routine patient management, only one set of information was collected and additional necessary information elicited. All clinical and support staff attending to patients in the CCC were oriented to the study and their roles clearly defined. A full-time study coordinator was employed to supervise the daily activities and ensure quality of the data.

The questionnaires and other tools used to collect information are in the appendix. The questionnaires and methodology used was pre-tested among CCC clients in Mbagathi Hospital in Nairobi. There was also a trial run of 5 clients to ensure the procedures were working and the logistics could be implemented as planned. The data from these clients were not included in the analysis.

3.7.1 Socio-demographic data and baseline household parameters

For all patients recruited in the study, demographics and household data were collected at recruitment, using a questioning schedule administered by a trained health provider.

3.7.2 Dietary consumption and diversity assessment

Dietary diversity information was collected using structured questionnaires at baseline and 3 month follow-up. The objectives of the component was to estimate diversity of food nutrients consumed by the individuals during the period of the

study for all the participants. The indicators used to measure nutritional outcomes was BMI, using measurements of weight and height, and MUAC.

Measurement of BMI: All patients recruited had their weights (in kilogram to the nearest 100g) and standing heights in centimetres taken. The BMI was computed from weight (in kg) divided by the square of the height (in meters).

Measurement of MUAC: Measurements were taken at the mid point of the left upper arm, with the palm extended and facing the thighs.

3.8 Ethical considerations

The Kenya Medical Research Institute Scientific Steering and Research Ethical Review Committees approved the study.

The Kenyan standard of care for people living with HIV/AIDS (PLWHA) did not include provision of food supplements either to patients starting ART or to patients being treated for opportunistic infections (OIs). Clients with BMI<16 were provided with food for 3-4 months (or until they attained a BMI>18.5), but their data was not included in the analysis.

Informed consent was obtained. Those who refused to participate in the study were not affected in their ability to receive ART or treatment for OIs. However, those who agreed to participate in the study had all the cost of the blood analysis required by the hospital and the study paid for.



The research team from KEMRI had a monitoring team to ensure that Good Clinical Practice procedures were followed throughout the study. The target group was 220 clients who had consented through the attached consent form. The study procedures were explained to the clients including procedures for blood samples collection and the universal safety precautions.

3.9 Recruitment and Training of Field Assistants

All the staff participating in the project were recruited from the hospital and trained according to the activities in appendix 3. This was done in the afternoon so as not to interfere much with the normal hospital activities.

3.10 Data Quality Assurance

Efforts were made to ensure consistency in the data quality. Staff participating in the study were trained on data collection and importance of completeness and accuracy in reporting. They were standardized in the methodology of collecting data using the questionnaires, collection of the blood samples, weighing and taking heights. The study coordinator monitored and supervised daily data completeness.

The weighing scales and blood analysis machines/equipment were calibrated and standardized at baseline and every 3 months during the study. Blood samples were also crosschecked in Laboratories in the country. An independent lab, SGS, monitored the quality of the food and nutrient content.

3.12 Data analysis and Management

Data was coded (open ended questions) and doubly entered into a microcomputer using Epi Info ver 6.04. Data validation was done before analysis. Data analysis involved at first level descriptive statistics (means, medians and standard deviations for continuous data; proportions and their 95% confidence intervals and frequency distributions for categorical data).

Second level analysis using Statistical Package for Social Sciences (SPSS) aimed at establishing significant differences between study groups for the various outcome variables. The analysis involved use of Chi-square to verify dependence of variables. Student's T-test was used to establish differences between the two groups, after confirming a normal distribution of the outcome variables.

For outcomes measured by continuous parameters, comparisons were made using ANOVA. Regression analyses were done using primary nutritional outcomes to control for covariates.

CHAPTER FOUR:RESULTS

4.1 Background Characteristics

4.1.1 Socio demographic and economic status

The socio-demographic and socio-economic characteristics evaluated included: age, gender, marital status, education, occupation, main source of food for the household and money spent on food. Of all the respondents 52.9% were on food supplements, while 47.1% were on counselling only. The total male participants were 39.7% while the females were 60.3%. Within the group on food supplements 39.0% were male and 61% were female. And for the group on counselling only 40.5% were male and 59.5% were female.

Distribution of the study population by gender and intervention group

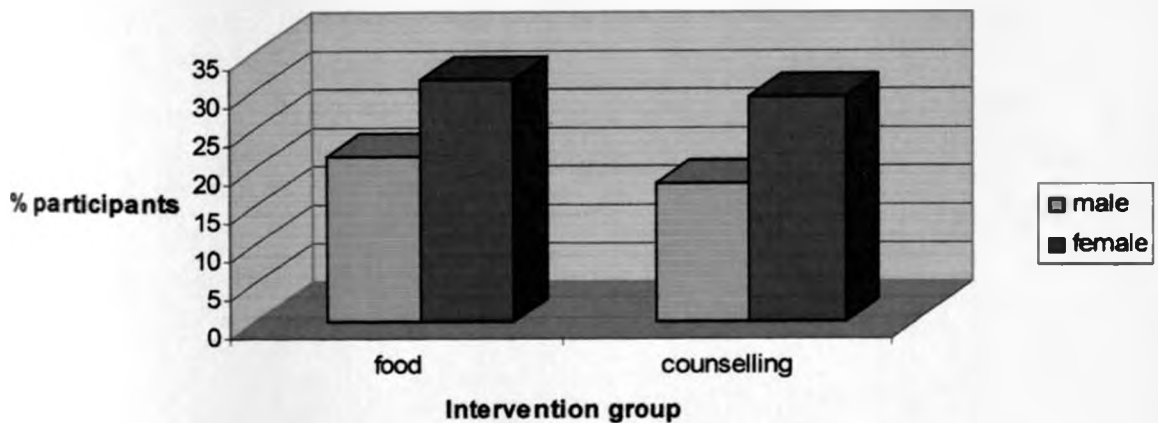


Figure 3: Distribution of study population by gender and intervention

Majority of the respondents (75.2%) were between the ages of 28-47 years. There was not much difference in the age groups between the two intervention groups except for

age 48-57, which had a 20% difference. This group represents 10% of the respondents, as indicated on table 2 and 3.

Table 2: Distribution of the study population by age and intervention.

Age in Years	% of respondents by Intervention groups		
	On food supplement	On counselling only	Total
18-27	54.3	45.7	14.0
28-37	54.9	45.1	45.2
38-47	48.0	52.0	30.0
48-57	60.0	40.0	10.0
58+	50.0	50.0	0.8

Table 3: Distribution of study population by age and gender

Gender	Age in Years					Total
	18-27	28-37	38-47	48-57	58+	
Male	1.6%	19.2%	13.6%	4.8%	-	39.2%
Female	12.4%	26.0%	16.4%	5.2%	0.8%	60.8%
Total	14.0%	45%	30.0%	10.0%	0.8%	100.0%

Marital status distribution of the study population

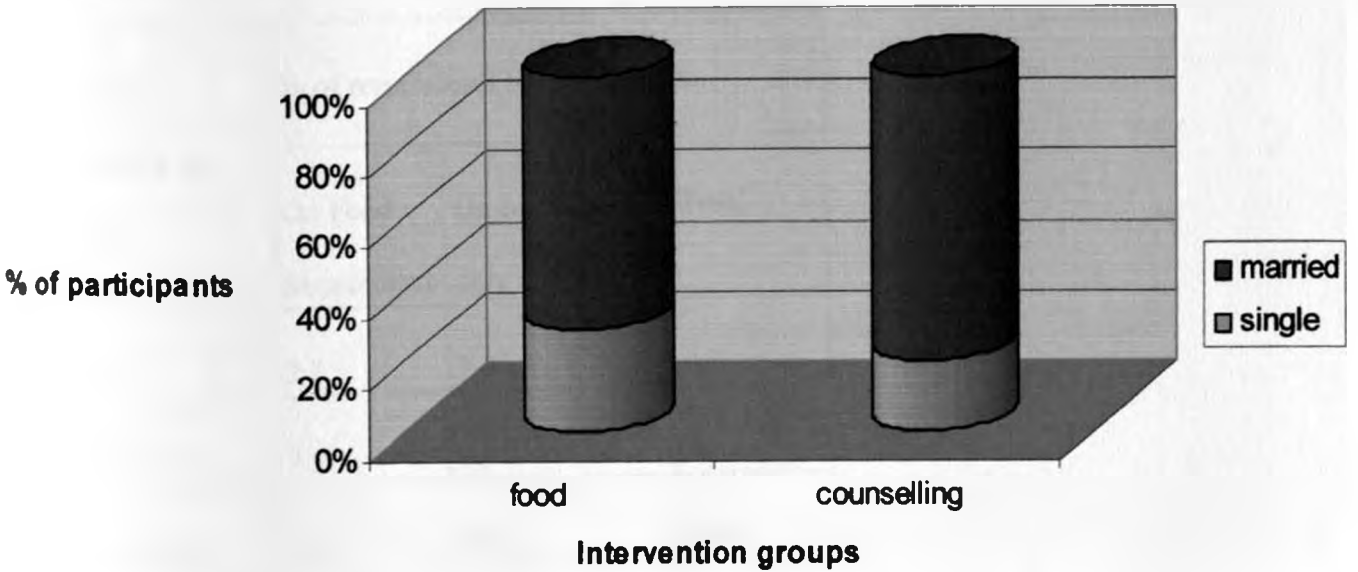


Figure 4: Distribution of study population by Marital status and Intervention.

There was a significant difference between those married(75.5%) and single(24.5%) of the total study population. This difference is across the intervention groups as shown on figure 4 .

Table 4:Distribution of study Population by Marital Status and gender.

Marital status	% of participants by gender		
	Male	Female	Total
Single	10.5	15.8	26.3
Married	32.9	40.8	73.7
Total	43.4	56.6	100

Among the single participants there were 5.3% more females than males. There was also a higher percentage(7.9%) of females among the married participants.

Table 5: Distribution of study population by Education level and intervention.

Level of Education in years	% of respondents by Intervention		
	On Food Supplement	On counselling only	Total
None	3.3	2.0	5.3
Primary 1-4	7.9	4.6	12.5
Primary 5-8	27.0	29.6	56.6
Secondary 9-12	-	0.7	0.7
Secondary 13-14	11.8	9.9	21.7
University	1.3	2.0	3.3

Table6: Distribution of study population by Education level and Gender

Level of Education in years	% of respondents by gender		
	Male	Female	Total
None	1.3	3.9	5.3
Primary 1-4	5.3	7.2	12.5
Primary 5-8	24.3	32.2	56.6
Secondary 9-12	0.7	-	0.7
Secondary 13-14	9.9	11.8	21.7
University	2.0	1.3	3.3

Table 5 compares the level of education and intervention group. The participants that had attained upper primary and over level of education were 83.2%. The majority of the participants attained between 5 and 8 years of formal education, and of these 43.8% were on food supplement while 56.3% were on counselling alone. The proportion of participants who had attained secondary and post secondary education were 30.3%. Of the total participants 45.3% females had over five years of formal education, compared to 34.9% of males as indicated on table 6.

Table 7: Main occupation by gender distribution of the study population.

Main Occupation	% of respondents by Gender		
	Male	Female	Total
Permanently Employed	8.6	5.3	13.8
Business	5.3	9.9	15.1
Temporary Employed	8.6	11.2	19.7
Farmer	10.5	9.9	20.4
Housewife	-	11.2	11.2
Unemployed	5.3	5.3	10.5
Others	5.3	3.9	9.2

Table 7 shows the main occupation distribution of the study population by the intervention group and gender. About half of the participants had an occupation that provided direct financial security. Of these 22.4% received food counselling only and 26.4% food supplements. While 26.4% were female and 22.5% were male. The rest of the participants depended on farming and assistance from spouses and other sources.

Table 8: Amount Spent per Month for the Household Distribution by Gender

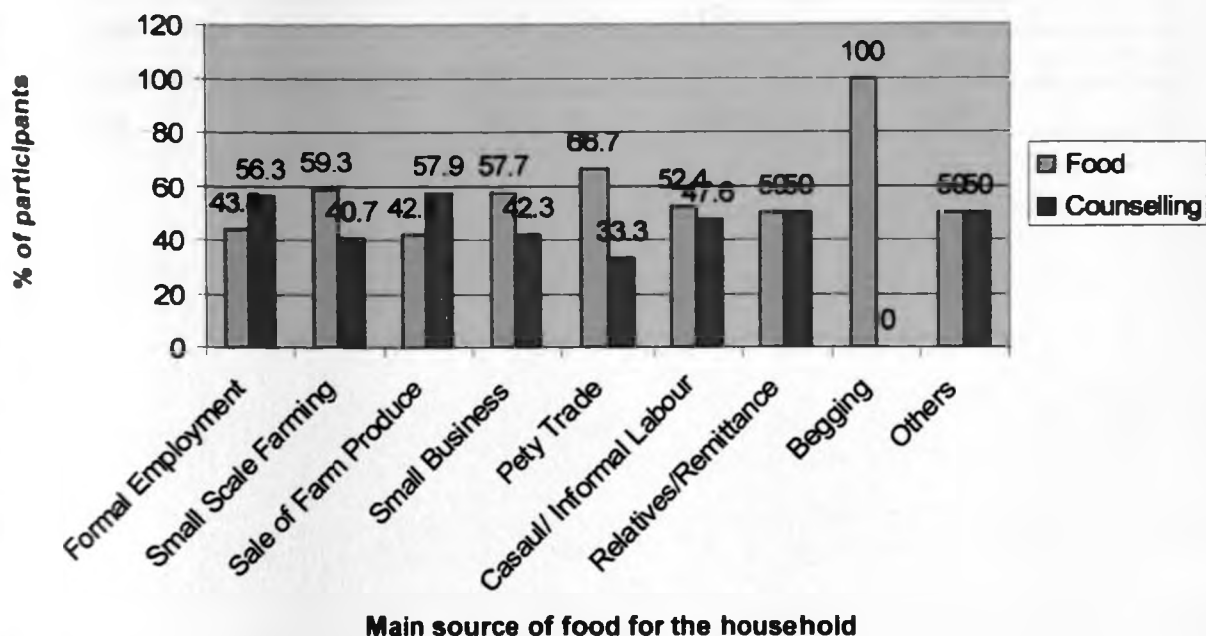
Amount(Kshs)	Amount spent on food/ month.% of participants		
	Male	Female	total
< 1000	0.7	0.7	1.4
1000-2999	17.9	26.5	46.9
3000-4999	13.1	17.1	30.2
5000-9999	9.2	11.4	21.0
10000-19999	0.7	0.7	1.4
20000-49999	1.3	0.7	2.0
No response	0	0	0

The respondents that had a household income of less than Kshs. 3,000 were 73.1%, yet 48.3% of the respondents spent a similar amount of their total income on food. Only 4.6% of the respondents earned a household income of over Kshs. 10,000. And 3.4% spent over Kshs. 10,000 on food purchase. Percentage of male participants earning Kshs. 3,000 and above was 12.5% compared to females at 10.1%. And 23.7% males spent 3,000 and above of their total earnings on food compared to 29.9% females.

Table 9: Income per Month for the household Distribution by Gender

Amount(Kshs)	Household income/ month. % of participants by gender		
	Male	Female	Total
< 1000	18.4	27.6	46.1
1000-2999	11.2	15.8	27.0
3000-4999	4.6	7.2	11.8
5000-9999	5.9	2.0	7.9
10000-19999	1.3	0.7	2.0
20000-49999	0.7	2.0	2.6
No response	1.3	1.2	2.6

Distribution of study population by main source of food for the household and intervention groups



Only 23% of the participants acquired their food from farm produce, while 66% from purchasing using income from employment, business or sale of farm produce. Majority of the participants who purchased food were casual labourers(30% of total participants). And only 11% depended on hand-outs. As shown in table 10, female participants were more involved in providing food for the household apart from the farm produce. Twice the number of females compare to males were engaged in small businesses, and about four times the number of females resorted to asking for assistance from relatives and other external sources.

Table 10: Distribution of Study Population by Main Source of Food for the Household and Gender.

Main Source of food for the household	% male participants	% female participants	Total
Formal Employment	2.7	3.5	6.2
Small scale farming	10.1	12.8	23.0
Sale of farm produce	6.6	8.2	14.8
Small business	3.1	7.0	10.1
Petty trade	1.2	0	1.2
Causal labour	12.8	19.8	32.7
Relatives/remittance/begging	2.3	8.2	11.3
Total	39.7	60.9	100

4.2 Nutritional Status

4.2.1 Assessment of Nutritional Status

This section contains the results on the clients nutritional status in terms of change in weight and body composition, using MUAC, BMI and body composition.

Table 11: Means of body weight and composition.

	Food supplement and counselling group		Counselling only group	
	Mean baseline	Mean month 3	Mean baseline	Mean month 3
BMI	17.31± 2.9	19.13±2.4	17.35±2.9	18.91±2.3
MUAC	21.35±2.3	23.10±1.8	21.96±2.2	23.54±1.9
% Body fat	24.25±2.9	24.4±2.0	24.30±2.8	23.91±2.8
% Lean mass	75.75±5.2	75.57±5.8	75.70±5.0	76.08±5.8

There was a slight change in BMI and MUAC within the intervention groups of 1.643 for BMI and 1.662 for MUAC over a period of 3 months. Yet the Students t-test analysis indicated no significant difference between and within the groups, food supplement and counselling and counselling alone, for BMI, MUAC, percentage body fat and percentage lean mass, at 5% significance level.

4.2.2 Dietary Diversity

This section presents the results of the food consumption of the study population. It aims at showing the dietary diversification of the respondents at the time of the study. Using the 12 food group individual dietary diversity (IDDS) the variety of food consumed by the clients was scored from 0-12.

Table 12: Distribution of study groups by food consumption.

Food Groups Eaten	Food supplement and counselling group		Counselling only group	
	% of responses baseline	% of responses month 3	% of responses baseline	% of responses month 3
Grain foods	7.9	1.6	93.3	98.4
Roots and tubers	76.7	75.6	23.6	23.4
fruits	86.8	80.3	13.4	18.8
Dark green vegetables	51.6	39.4	49.1	58.6
Eggs	87.8	83.5	12.3	14.8
Organ meat	96.0	96.1	4.0	2.3
Other meat	82.3	78.0	18.0	21.1
Fresh or dried fish	93.4	90.6	6.7	7.8
Legumes and Nuts	54.2	40.9	46.4	57.8
Milk/dairy products	23.0	24.4	78.0	75.8
Foods made with fat and oils	25.7	14.2	75.3	85.2
Sugar and Honey	32.8	26.8	68.1	73.4

Table 12 shows the consumption of individual food groups for the 2 intervention groups. Majority of the respondents on counselling only consumed grain foods and not roots and tubers, unlike those on food supplement, who consumed the vice versa. The respondents on food supplement consumed more food groups than those on counselling only at baseline. Though after 3 months majority did not change their dietary diversity. The group on counselling only had a lower dietary diversity at baseline and improved after 3 months. The individual dietary diversity scores are shown below.

Table 13: Distribution of the study group by the intervention and IDDS

Intervention group	Individual dietary diversity scores		
	0-4	5-8	9-12
Food supplement	Roots and tubers Fruits Organ meat Eggs	Roots and tubers Fruits Organ meat Eggs Dark green vegetables Fresh or dried fish Legumes and nuts Other meat	Roots and tubers Fruits Organ meat Eggs Dark green vegetables Fresh or dried fish Legumes and nuts Other meats Grain foods Foods made with fats/ oils Milk and milk products Sugar and honey
Counselling only	Grain foods Milk and milk products Foods made with fats and oils Sugar and honey Legumes and nuts Dark green vegetables	Grain foods Milk and milk products Foods made with fats and oils Sugar and honey Dark green vegetables Legumes and nuts Fruits Other meat	Grain foods Milk and milk products Foods made with fats and oils Sugar and honey Dark green vegetables Legumes and nuts Fruits Other meat Fresh and dried fish Eggs Organ meat

The study established that for those on food supplements 11% scored 0-4, 35% scored 5-8 and 54% scored 9-12 at baseline. After 3 months the distribution was 13%, 39% and 48% for the respective scores. While those on counselling alone 15% scored 0-4, 51% scored 5-8 and 34% scored 9-12%. After 3 months 10.6% scored 0-4, 51.2% scored 5-8 and 38.2% scored 9-12. The highlighted food groups are those that the respondents introduced into their diet after 3 months.

4.2.3 Morbidity

Asked about their illness one month preceding the interview, it was indicated that among those on food supplements 59.9% were ill, and 69.2% of those on counselling only were ill, at baseline. Within the 3 months of study 47.2% of those on food supplements were ill, and 66.1% of those on counselling only were ill. The most common symptoms were weight loss(57.6%), oral thrush(20.7%) and diarrhoea(17.8%). After 3 months there was a notable improvement especially for these symptoms(22.0%, 7.1% and 9.4% respectively).

Table 14: Incidence of Illness Distribution of the Study Population by Intervention Group in Percentages.

Symptom	Intervention Group				Total	
	Food supplement		Counselling only		Month 0	Month 3
	Month 0	Month 3	Month 0	Month 3		
Mouth/throat ulcers	53.4	25.0	46.6	75.0	12.6	6.3
Passing black stool	62.5	66.7	37.5	33.3	2.6	2.4
Oral thrush	52.8	66.7	47.2	33.3	20.7	7.1
Anaemia	53.2	100.0	46.8	0.0	8.5	0.8
Diarrhoea	53.6	66.7	46.4	33.3	17.8	9.4
Night blindness	41.7	66.7	58.3	33.3	5.1	2.4
Weight gain	60.0	52.4	40.0	45.6	15.0	53.5
Weight loss	53.6	85.7	46.4	14.3	57.6	22.0

4.3 Association of Change in Nutritional Status with Other Variables

Various independent variables; age, gender, current marital status, education level, main occupation, main source of household income, main source of food for the household, and money spent on buying food were statistically tested against dependant variables BMI, MUAC, body fat content and lean mass content using backward linear regression. There was no significant association of change in MUAC, body fat content and body lean mass with these independent variables.

However for BMI there was significant association with money spent on food($p=0.018$) and main source of food for the household($p=0.041$). The main source of food showed a weak correlation($r=0.16$), while money spent on food indicated a negative correlation ($r= -0.20$) with change in BMI. There was a positive and weak correlation($r= 0.33$) between the two independent variables.

The odds ratio analysis indicate that those who depend on farm produce are 1.8 times more likely to improve in weight than those who purchased their food.

CHAPTER FIVE: DISCUSSION

5.1 Social Demographic Profile

The study established that the females were more than the males in the study population. According to the Kenya HIV/AIDS Data Booklet 2005, Kenyan women are particularly vulnerable to HIV and AIDS. Of the 1.1 million adults infected with HIV, twice as many women as men are positive. HIV prevalence among women aged 15–49 years is 6.7%, compared with 3.5% in men of the same age group. Gender differences are most striking in the youngest age group, 1.6% for the males and 12.4% for the females. There is a similar trend nationally, where among young women the prevalence is 4.4% while it is only 0.8% for young men. Available evidence indicates that girls start sexual activity earlier than boys, have large numbers of sexual partners, a high prevalence of sexually transmitted infections, and are victim to a high incidence of violent sexual contact.

The higher percentage of women could also indicate that more women tested for HIV/AIDS than men. It also could indicate that they tested as a referral from the PMCT centre.

In most households it is the woman who prepares the meals and directly can implement the knowledge she had acquired from nutritional counselling. Therefore, with a higher percentage of the participants being women there is a possibility of a higher number of participants practising the knowledge they received from the nutritional counselling.

The education level of the study population was quite high, with 5.4% illiterate, 63.8% primary education(complete or incomplete), 37.2% secondary education and 3.1% above secondary education as compared with CBS figures; 22.9% illiterate, 59.6% primary education(complete or incomplete), 7.1% secondary education and 3.5% above secondary education. Therefore the level of education might have played a role in improving the economic status of the participants. They were able to secure employment, manage their businesses well, and improve their farming practises. Higher level of education also contributed towards better assimilation of the nutritional counselling and implementation utilizing the food from household production or/and purchase.

The study also established that majority of the participants were employed with 43% in informal employment. And 27% mainly depended on farming as a source of income.

The study area had households with mostly farm plots of less than 2.5 acres and most of them practised rain-fed subsistence farming which cannot sustain food supply for the whole year, just like approximately 80% of 37.2 million Kenyans (revised population projection for Kenya 2000–2020, Central Bureau of Statistics, August 2006) who live in rural areas and subsist almost entirely on agricultural production. Which means that many households had to complement this with other means of income like employment, business and hand-outs. Maragua District does not have many opportunities for employment but it is neighbouring commercial towns like Thika, Karatina, Embu, Muranga and Nairobi. Therefore most of the participants were migrant employees within the surrounding areas.

Incidentally 64.7% of the participants spent Kshs. 3,000 and over on food purchase per month yet only 36.6% earned a similar amount. A 2006 report states that 79% of all HIV/AIDS affected household heads in the informal sector had an annual income of less than KES 15,000 a year (*NACC 2006b*). This means that majority of the households had other sources of income to sustain their food requirements.

5.2 Nutritional Status

The study findings show that there was an improvement in weight for 86.7% of the participants over a period of 3 months. However the change was not significant over the period of study between and within the study groups.

All participants received nutritional counselling which appears to have been successful in influencing change in dietary consumption, especially for those who were not on food supplements. There was an increase in consumption of plant and animal protein, grains and fats to meet their daily dietary requirements, which had increased due to the HIV/AIDS status. For symptomatic PLWHA energy needs increase by 20-30%, and protein intake at 12-15% (*NASCOP 2006*).

The group on food supplement and counselling reduced their food consumption of grains, legumes, green vegetables and fruits. These are food groups represented in the food supplement as it was a blend of maize, soya, sugar, palm oil, and micro-nutrients pre-mix. Since they were aware of the composition of the supplement some could have decided not to adhere to the nutritional counselling and assume that the supplement would cover for their dietary diversity. The food supplement provided for only a third

of the daily dietary requirement and yet they still managed to increase their BMI and MUAC. Which means that for those whose BMI and MUAC increased could have maintained their normal dietary intake and just added the food supplement which resulted into increased body weight.

The study shows that counselling only increased their dietary diversity by introducing legumes, nuts and other sources of animal protein apart from beef. This provided a proper mix of amino acids which are necessary for adequate support of growth, maintenance and repair of body tissues, and meet immune functions in both HIV-infected and uninfected persons.

They also introduced dark green vegetables which provided micro-nutrients and vitamins, necessary for production and function of proteins, enzymes, hormones, and the immune system.

5.3 Morbidity

The most common diseases was oral thrush and diarrhoea. Other studies show that diarrhoea, a very common symptom of HIV and AIDS, affects 90 percent of PLWHA and results in significant morbidity and mortality (Katabira,1999; Monkemuller and Wilcox, 2000).

After 3 months those on food counselling only had reduced the incidence of oral thrush and diarrhoea. This could have been because of increasing their dietary diversity which improved their immune system. Those on food supplements increased the incidence of both diseases, probably because they did not increase their diet diversity.

Weight loss was another common symptom among the participants. Those on food supplements had increased incidence of weight loss after 3 months compared to those on food counselling only. Majority of participants on food supplement reduced their food consumption replacing with the food supplement. And those on nutritional counselling reduced their percentage in weight loss.

5.4 Association of Socio-economic and Demographic Factors on Change in BMI

The socio-demographic and socio-economic characteristics evaluated included: age, gender, marital status, education, occupation, main source of food for the household and money spent on food. All these variables did not show significant differences between the two intervention groups. Though the main source of food for the household and money spent on food influenced the changes in BMI. The main source of food had a positive influence on BMI. The study population being a rural area did depend on farm produce as a source of food for the households. And at the time of the study (August-October) most of the farms had produce that was ready for harvesting. Some of the households sold produce and purchased food to supplement farm production therefore increasing the opportunity to consume a higher diet diversity. Therefore those who depended on household source of food were 1.8 times more likely to improve in their nutritional status.

On the other hand the amount of money used on food had a negative relationship with the nutritional status. There was a negative influence on change in BMI when there was increase in amount of money spent on food in the household. The Engel's law states that

he proportion of a family's budget devoted to food declines as the family's income increases. This means that the income-limited households tend to use more of the income on food. Therefore the limited resources will be used to purchase starchy staples in limited amounts. And this could lead to negative effect to the nutritional status of the individuals within the households.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The study was not able to establish that food supplements lead to increased weight gain and change in body composition within the study period. There was no difference in the group that was provided with food supplements and the group that did not, in terms of change in weight and body composition. This could have been because the study period was too short.

The Nutritional counselling alone effects increase in individual dietary diversity and food consumption. The nutritional counselling provided information that lead to change in the eating habits. At the same time, receiving food supplements had a negative influence on the consumption and diet diversity. Some of the recipients didn't adhere to the counselling assuming that the food supplement would replace their daily dietary intake.

Socio-demographic and socio-economic factors influence change in weight gain. Higher level of education, gender and source of food for the household influenced change in body weight. Women play an important role in household food security as they are involved in uplifting the economic status of the household.

The main source of food for the household significantly influenced the chances of improving the nutritional status of the participants. In times when there is enough farm produce, farms are a good source of food for the household in a rural set-up.

The percentage of the household budget used on food purchase will influence change in the nutritional status of individuals in that household. As the percentage increases there is decrease in the nutritional status.

2 Recommendations

Nutritional counselling should be included in nutritional management of PLWHA **intervention programmes** because it can effectively improve the diet consumption.

Though effective, food supplementation should only be used in resource limited **conditions**, and after nutritional counselling alone has failed.

Most of the food intervention programmes should mostly target women to be effective.

The stakeholders should ensure that the economic levels of most rural communities **improve** so as to ensure food security for PLWHA. Because of their fitness levels and **irregular rain patterns**, farm production may not be sustainable. Before embarking on **nutritional interventions** they should take into account the economical status of the **households targeted**.

A similar study over a longer period is recommended to effectively analyse the effects **of food supplements** on change of body mass and composition.

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APPENDICES

Appendix 1: Questionnaire

Socio-Demographic, Clinical and Nutrition Assessment

Instructions to Research Assistant: Circle and/or write the correct response.

1. BASIC INFORMATION

1.1 Date of interview (dd/mm/yy) _____

1.2 Intervention group (1) food supplement (2) No supplement

1.3 Name of Study Participant _____

1.4 Age of Participant _____

2. SOCIO-DEMOGRAPHIC INFORMATION

2.1 Sex/Gender of participant [1] Male [2] Female

2.2 What is your current marital status?

[1] Single (not married and not living with a partner) [5] Divorced

[2] Married (monogamous) [6] Widowed/widower

including car repair, carpentry etc)

[9] Housewife

[4] Agricultural/forestry worker

[10] Unemployed

[5] Business (self employed)

[11] Attendant in hotels, guest house,
bars, or clubs

[6] Professional (Teacher, doctor,
nurse, manager, accountant etc)

[12] Other (specify) _____

3. SOCIO-ECONOMIC INFORMATION

3.1 Has your main source of earning or livelihood changed over the course of last 1 year?

[1] No [2] Yes

3.2 What is the income of your household (choose from the categories below in Kenyan Shillings)?

[1] Less than 1000 [5] 10,000-19,999

[2] 1,000-2,999 [6] 20,000-49,999

[3] 3,000-4,999

[7] 50,000+

[4] 5,000-9,999

3.6 How much money in Kenyan Shillings do you usually spend on buying food for one day in your household _____

5. NUTRITIONAL AND CLINICAL ASSESSMENTS

Perform the following examinations and fill the data where indicated.

Measures Months	Weight	Height	BMI	Fat%	Lean%	BIA
0						
1						
2						
3						

Appendix 2: 24-Hour recall

24-HOUR RECALL ON INDIVIDUAL FOOD DIVERSITY

1. BASIC INFORMATION

1.1 Date of interview (dd/mm/yy)

1.6 Name of Study Participant

2-HOUR RECALL

2.1 Yesterday (during the day and at night), did you eat any of the following group of foods or food items?

Food Category and Food Items

Write:[1]=No [2]=Yes

A. Grain Foods

1. Ugali (made of maize, millet, sorghum flour) 2. Bread 3. Rice
4. Spaghetti/noodles/pasta 5. Chapati Boiled/roasted maize 6. Pancakes Biscuits
7. Cake Donut/fried dough 8. Rice cake (vitumbua) Plantain (matoke)

B. Roots/Tubers and Vegetables with Yellow or Orange Inside

1. Carrot 2. Pumpkin 3. Squash with orange inside 4. Yams with orange inside

C. Other Roots/Tubers

1. Irish Potatoes 2. Cassava 3. Taro/arrow roots 4. White Yams

D. Fruits that are Rich in Vitamin A

1. Mango 2. Papaya

E. Dark Green, Leafy Vegetables

1. Lettuce (dark green) 2. Pumpkin leaves 3. Spinach

F. Other Fruits or Vegetables

1. Amaranths / mchicha 2. Bitter tomatoes 3. Cabbage 4. Cassava leaves

5. Chinese cabbage 6. Cow peas leaves 7. Cucumber 8. Eggplant 9. Green pepper

10. Lettuce 11. Okra 12. Tomato 13. Mushrooms 14. Wild vegetables

15. Orange 16. Tangerine 17. Lemon 18. Ripe banana 19. Plums

20. Avocado 21. Passion fruits 22. Grapefruits 23. Apples 24. Peaches

25. Guava 26. Watermelon 27. Pears 28. Pineapple 29. Pomegranate

30. Jackfruit 31. Wild fruits

G. Eggs

1. Any Eggs (hens, duck etc)

H. Organ meats

1. Liver
2. Kidney
3. Hearts
4. Intestines

I. Other Meat (beef, poultry, pork etc)

- 1 Beef (including from wild animals)
2. Pork
- 3 Chicken
3. Goat meat
4. Lamb
5. Rabbit meat
6. Duck
7. Turkey

G. Dried or Fresh Fish

1. Fresh or Dried fish
2. Smoked fish

H. Legumes and Nuts

1. Beans
2. Cow peas
3. Chick peas
4. Green mung
5. Green peas
6. Pigeon peas
7. Bambara nuts
8. Ground nuts (peanuts)
9. Cashew nuts / macadamia
10. Soya beans

I. Milk and Dairy Products

1. Cow's milk (include maziwa mala)
2. Goat's milk
3. Ice cream
4. Cheese
5. Yogurt

J. Foods made with Fats and Oil

1. Margarine spread
2. Butter spread
3. Foods made with vegetable oil
4. Foods made with palm oil
5. Foods made with ghee

(Examples of foods made with oils/fats: Fried eggs, Fried potatoes/chips, Fried cassava, Fried dough)

K. Sugar and Honey

1. Sugar
2. Honey
3. Brown sugar cake (sukari guru?)

Appendix 3: Training schedule.

Training Day	Activity
1	Introduction to the project and other participants
2	Practical training on taking MUAC, Weight, Height and use of BIA machine.
3	Training on administration of Questionnaires
4	Demonstration on preparing the food supplement/blood sampling
5	Training on nutritional counselling
6	Trial run