

**Effect of food supplementation on health-related quality of life among
HIV-infected adults attending Naivasha District Hospital**

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Science in Public Health in the Jomo Kenyatta University of Agriculture
and Technology**

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DECLARATION

This Thesis is my original work and has not been presented for a degree in any other university.

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DEDICATION

This study is dedicated to my mother Ruth V. Alumasa and late father Henry M. Alumasa for always believing in me.

“Keep your dreams alive. Understand that to achieve anything requires faith and self belief, vision, hard work, determination, and dedication. Remember all things are possible for those who believe.”

Gail Devers

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DEFINITION OF TERMS

Quality of life:	Individual's perception of his/her position in life in the context of the culture and value systems in which he/she lives, and in relation to his/her goals, expectations, standards and concerns.
Health Related Quality of Life:	It represents the functional effects of an illness and its consequent therapy upon a patient, as perceived by the patient including physical functioning, social functioning, role functioning, psychological functioning and socio-economic environment.
Physical functioning:	Comprises of all movements in everyday life, including work, recreation, and sports activities and has been categorized in levels of intensity from light to moderate to vigorous.
Psychosocial functioning:	Assesses the patient's own thoughts about body image and appearance, negative feelings, positive feelings, self-esteem and personal beliefs and includes feelings of emotional distress, depression and anxiety and how they relate to their ability to develop, maintain, and nurture major social relationships.
Fortified blended flour:	Partially cooked mixture of cereals, pulses, fats and fortified with micronutrients mainly used as supplemental food in the management of moderate and mild under-nutrition.
Chronic energy deficiency:	CED is defined as a "steady state" where an individual is in

energy balance, i.e. the energy intake equals the energy expenditure, despite the low body weight and low body energy stores.

ART clients: Clients beginning ARVs treatment, begun within the past 2 weeks or will begin within the next 5 weeks.

Pre-ART clients: Clients not taking ARV drugs and not due to begin in the next 5 weeks

Stigma: Stigma is an attribute, behavior, or reputation which is socially discrediting. It can also be described as a "process of devaluation" of people who are either living with or associated with HIV/AIDS.

Discrimination: Discrimination follows stigma and is the unfair and unjust treatment of an individual based on his or her real or perceived HIV status (UNAIDS, 2003).

LIST OF ABBREVIATIONS

AIDS:	Acquired Immune Deficiency Syndrome
ART:	Antiretroviral therapy
ARV:	Antiretroviral drugs
BIA:	Bioelectric impedance analysis
BMI:	Body Mass Index
CBS:	Central Bureau of Statistics
CCC:	Comprehensive Care Centre
CDC:	Centre for Disease Control
CED:	Chronic energy deficiency
FANTA:	Food and Nutrition Technical Assistance
FBF:	Fortified blended food
FBP:	Food by prescription
FS:	Food supplement
HIV:	Human Immunodeficiency Virus
HRQOL:	Health-related Quality of Life
KAIS:	Kenya AIDS Indicator Survey
KEMRI:	Kenya Medical Research Institute
KENQOL:	Kenya Quality of Life
MoH:	Ministry of Health
MUAC:	Mid Upper Arm Circumference
NASCOP:	National AIDS and STI Control Programme

NC:	Nutrition counseling
OIs:	Opportunistic infections
PLWHA:	People Living with HIV/AIDS
QOL:	Quality of Life
SF 36:	Short form 36
TB:	Tuberculosis
TSFT:	Triceps Skin Fold Thickness
UNAIDS:	Joint United Nation Programme on HIV/AIDS
WHO:	World Health Organization
WHOQOL:	World Health Organization Quality of Life

ABSTRACT

Measurement of quality of life in HIV/AIDS is gaining relevance as an outcome measure. In Kenya, there are no published studies that look directly at the effect of food supplementation on health related quality of life (HRQOL) of people living with HIV/AIDS (PLWHA). This randomized controlled study with 3 months follow up aimed at establishing the effect of food supplementation (Foundation plus; a mixture of maize and soya flour, sugar, palm oil and fortified with multiple micronutrients produced by Insta Foods Kenya Ltd) and nutrition counseling on the nutritional status and HRQOL measures of PLWHA. A block random sampling technique was used on a sample size of 226 subjects. Data was collected from Naivasha District Hospital using a questionnaire. Data entry and analysis were done using SPSS version 11.5. Data analysis involved descriptive statistics, paired t-test, student's t-test, Mann-Whitney U-test and Chi square to show statistical differences after the intervention. At baseline, subjects had poor nutritional status as evidenced by BMI below the WHO cut-off for malnutrition. In addition, poor physical activity level and self-reported health status coupled with multiple signs and symptoms indicated poor HRQOL. After the intervention, both groups had significant increase in mean weight and BMI ($P < 0.01$). However, no significant difference in nutritional status and HRQOL between the groups was achieved. The intervention with a food supplement and nutrition counseling had a positive impact on nutritional status and so did nutrition counseling alone. Consequently, the rationale for food supplementation of undernourished PLWHA needs to be reviewed as nutrition counseling alone was seen to have a similar impact in comparison to the food supplemented group.

CHAPTER ONE

INTRODUCTION

1.1 Background

HIV/AIDS has had and continues to have devastating impact on all sectors of the society. Since the first cases of acquired immunodeficiency syndrome (AIDS) were reported in 1981 (CDC, 1981), infection with the human immunodeficiency virus (HIV) has grown to pandemic proportions. The pandemic remains the greatest health challenge of this age with the United Nations stating that the AIDS phenomenon is nothing short of war on humanity (UNAIDS, 2002). Global data shows that 33.2 million people (1.1%) are infected with the HIV virus, 2.5 million became newly infected and 2.1 million people died of AIDS (UNAIDS/WHO, 2009). Sub-Saharan Africa remains the region that is worst affected by HIV/AIDS with an estimated 22.4 million (5.2%) people living with HIV (PLWHA) representing over 68 % of the world's PLWHA (UNAIDS/WHO, 2009). In Kenya, HIV/AIDS is one of the greatest social and economic challenges (NASCOP, 2005) with approximately 1.4 million people aged between 15-64 years infected with HIV/AIDS thus giving a prevalence of about 7.1% (KAIS, 2007).

Nutrition has been acknowledged as an important determinant in the rate of HIV progression (Bogden *et al*, 2000). Adequate nutrition is necessary to maintain the immune system, manage opportunistic infections, optimize response to medical treatment, sustain healthy levels of physical activity, and support optimal quality of life for PLWHA. Good nutrition may also contribute to slowing the progression of the disease (Castleman *et al*,

2004) by boosting the immune system and has been shown to positively influence the health related quality of life (HRQOL) of PLWHA (Owusu and Twenefour, 2005). PLWHA are at greater risk of malnutrition (under-nutrition) than non-HIV-infected adults. This manifests as wasting, weight loss and/or reduced immunity and is usually as a result of deficiency in macro- and micronutrients.

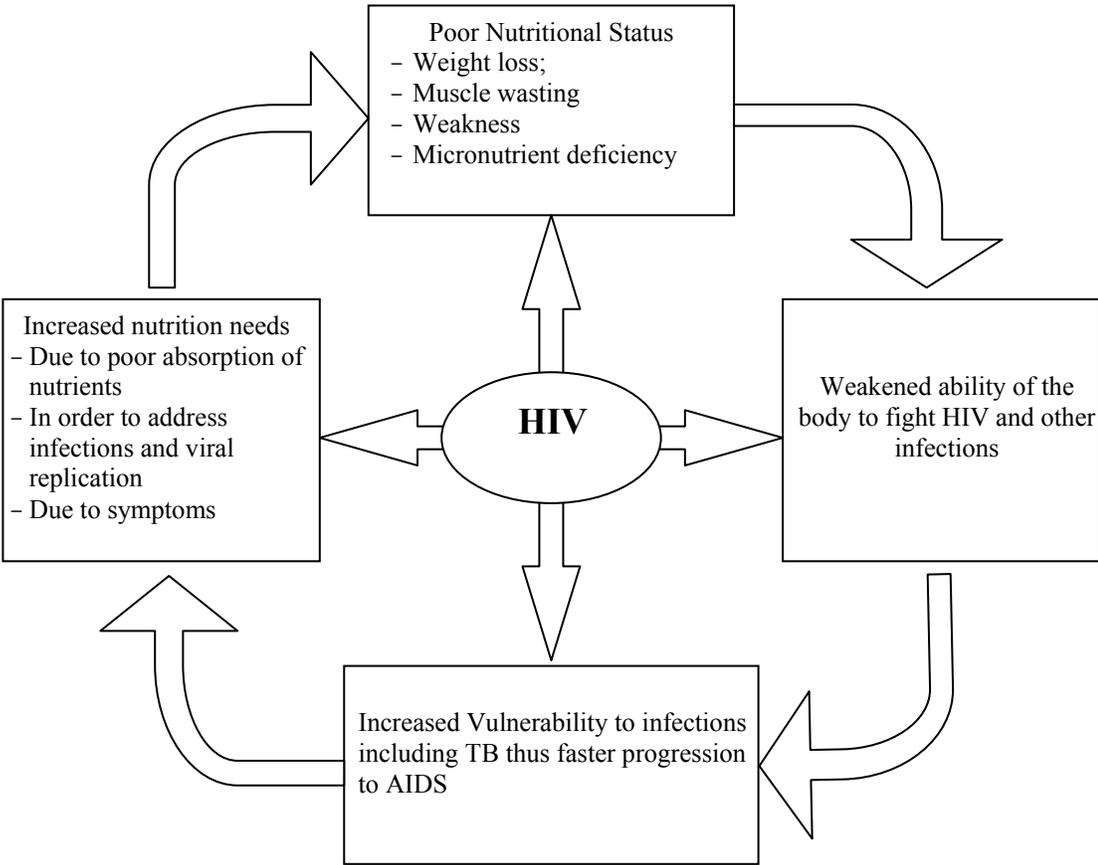


Figure 1.1: The Cycle of malnutrition and infection in the context of HIV/AIDS

Source: Adapted from Nutrition Management in Comprehensive Care Centres in Kenya (Trainer’s Manual, 2007)

The 1996 World Food Summit in Rome defined food security as a state “when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life” (FAO,1996). People's food and nutrition security needs vary over their life cycles, as do the implications for their physical and mental health well-being and ultimately quality of life (QOL). Food insecurity has been associated with increased HIV risk behaviour including inconsistent condom use, sex in exchange food or money, and lack of control over sexual relationships (Weiser *et al*, 2007). Therefore, targeted food assistance plays an important role in decreasing HIV transmission risk (Weiser *et al*, 2007) especially in the Horn of Africa (Djibouti, Eritrea, Ethiopia, Kenya, Somalia, Sudan and Uganda) where approximately 70 million people suffer from chronic food insecurity (FAO, 2000). In Kenya, 43.9% of the population is food energy deficient (Smith *et al*, 2006). Therefore, provision of nutritional support is an important component of comprehensive care for PLWHA, particularly in resource-limited settings where undernutrition and food insecurity are endemic.

1.2 Study justification

In order to fully evaluate any healthcare intervention, outcome measures of importance to the patient are required as well. According to O'Young and McPeck (1987), few trials consider QOL variables as outcomes despite the primary objective of any intervention being to enhance QOL. Measurement of HRQOL can assist in understanding the long-term effects of disease and treatment on HIV+ persons (Campsmith *et al*, 2003). It also provides a feasible, reliable and valid method to assess the impact of HIV/AIDS and interventions to

improve patient outcomes in rural and peri-urban African settings. Most QOL investigations of PLWHA have been undertaken on hospitalized patients. However, as HIV is increasingly being managed as a chronic illness, it becomes necessary for health care providers to understand HRQOL among PLWHA as it is viewed as a useful tool for monitoring patient progress (Huba *et al*, 2000). Numerous studies have been done on PLWHA QOL (Mast *et al*, 2004; Préau *et al*, 2004). However, there is little existing published work directly assessing the effect of food supplementation on HRQOL of PLWHA. Assessing HRQOL is necessary to a comprehensive evaluation of health care, considering the negative impact on HRQOL due to physical discomfort, emotional depression and social stigma associated with the progression of HIV/AIDS (Riedinger *et al*, 2001). Therefore, unless QOL aspects are quantified and reported in trials, they will be ignored or undervalued in health policy decisions. Measuring HRQOL can provide important information about the effects of disease progression, treatment prognosis and risk stratification that is not captured in laboratory measurements.

It is important to build an evidence-based understanding of the contribution of food supplements to the HRQOL and physical status of beneficiaries, not only to better justify the provision of such assistance but also to improve the design and implementation of targeted food supplementation programs.

1.3 Research questions

- a. Does food supplementation improve the nutritional status and HRQOL measures of nutritionally vulnerable adult PLWHA?
- b. Does nutrition counseling improve the nutritional status and HRQOL measures of nutritionally vulnerable adult PLWHA?

1.4 Objectives

1.4.1 General objective

To determine the effect of food supplementation and nutrition counseling on the nutritional status and HRQOL measures of nutritionally vulnerable adult PLWHA

1.4.2 Specific objectives

- a. To determine the nutritional status and HRQOL measures of nutritionally vulnerable adult PLWHA before food supplementation and nutrition counseling.
- b. To establish the effect of food supplementation and nutrition counseling on the nutritional status and HRQOL measures of nutritionally vulnerable adult PLWHA.
- c. To establish the effect of nutrition counseling alone on the nutritional status and HRQOL measures of nutritionally vulnerable adult PLWHA.

1.5 Hypothesis

- Food supplementation with fortified blended flour (FBF) and nutrition counseling of nutritionally vulnerable adult PLWHA significantly improves their nutritional status and HRQOL measures.
- Food supplementation with fortified blended flour (FBF) and nutrition counseling of nutritionally vulnerable adult PLWHA significantly does not improve their nutritional status and HRQOL measures.

CHAPTER TWO

LITERATURE REVIEW

FOOD SUPPLEMENTATION AND NUTRITION COUNSELING IN THE MITIGATION OF NUTRITION VULNERABILITY AMONG PLWHA AND THEIR INFLUENCE ON HRQOL

2.1 Nutritional vulnerability

Nutritional vulnerability is defined as the presence of risk factors for under-nutrition (Hewitt *et al*, 2006) and includes social, economic, physical and psychological risk factors. The degree of nutritional vulnerability of individuals, households or groups of people is determined by their exposure and ability to cope with the risk factors. Nutrition vulnerability may lead to malnutrition; a commonly used term linked to inadequate food intake, poor uptake of nutrients by the body, and poor use and storage of nutrients. Malnutrition in HIV infection is associated with progressive muscle wasting, reduced immunity, increased morbidity and mortality (Chlebowski *et al*, 1989) and decreased functional performance which negatively impact on HRQOL of PLWHA (NASCO, 2005).

In addition to medical and physiological factors, psychosocial factors such as depression, knowledge of bodily functions and key nutritional principles may impede appetite or the ability to prepare meals. Additionally, socio-economic (homelessness, financial

independence and access to food); functional status (the ability to shop for and prepare food) and cultural factors (dietary intake barriers and habits) may also contribute to poor nutrition status (Ayoob, 2000).

Malnutrition resulting from severe weight loss has been associated with reduced immune competence, increased frequency of opportunistic illnesses and increased mortality (Colecraft, 2008). Weight loss is a reliable index of nutritional vulnerability commonly associated with HIV/AIDS and has been correlated with increased morbidity and mortality (Kotler, 1998). Weight loss has been found as being a better predictor of mortality than lean or fat tissue in ART patients (Tang *et al*, 2002). Weight loss is often the event that begins a vicious cycle of increased fatigue and decreased physical activity including the inability to prepare and consume food. A study by Dangerfield *et al* (1994) observed that generalized wasting affects the survival, QOL and self image of PLWHA and is negatively associated with HIV outcome (Chlebowski *et al*, 1989). This has an effect on the entire family when infected adults become too debilitated to work hence are unable to provide for both themselves and their dependants and require continuous care during episodes of illness. It creates a vicious malnutrition-HIV/AIDS cycle which ultimately undermines health and HRQOL of PLWHA leading to increased morbidity and mortality.

2.2 Nutritional assessment methods

According to Grant and DeHoog (1999), nutrition assessment is an in-depth evaluation of both objective and subjective data related to an individual's nutritional status, food and

nutrient intake, lifestyle, and medical history. Nutritional assessment of PLWHA is necessary because they experience rapid and dynamic changes in body composition including decreased weight, body cell mass and fat accumulation (FANTA 2003), some of which have detrimental implications for the individual's morbidity and mortality. Initial nutritional screening and assessment gathers information on the current nutritional status of PLWHA, the adequacy of their diet, their food habits and dietary constraints. Screening and assessment of anthropometric measurements can identify poor eating behaviors and recommend ways to improve the diet. The major purpose of nutritional assessment is therefore, to determine the severity of nutritional impairment and its probable causes. The assessment leads to a plan of intervention designed to help the individual either maintain the assessed nutritional status or attain a healthier status. The nutrition assessment methods include: *anthropometric, biochemical, clinical, and dietary assessment.*

Anthropometric measurement provides the single most portable, universally applicable, inexpensive and non-invasive technique for assessing the size, proportions, and composition of the human body. Anthropometry and bioelectrical impedance analysis (BIA) are commonly used field techniques in measuring body composition. Both are indirect measurements of body composition, since they require comparison with a reference (Ludy *et al*, 2005). Anthropometric measurements are a good measure of the nutritional status of vulnerable groups and individuals for example PLWHA. Opara *et al* (2007) focused on anthropometry in comparing nutritional status in HIV+ and HIV- children.

Other studies have also used measurements of body mass index (BMI) and mid upper arm circumference (MUAC) to assess nutritional status in HIV+ subjects (Song *et al*, 2007).

Biochemical laboratory tests based on blood, plasma/serum and urine include assessing the levels of hemoglobin, glucose, albumin, liver enzymes, iron, lipids, insulin, vitamins, trace elements, free testosterone, and renal function which are important indicators of nutritional status as well as clinical nutrition health status.

Clinical data provides information about the individual's medical history, including acute and chronic illness. The clinical components that closely influence nutritional status and its evaluation include assessment of altered nutritional requirements and psychosocial that may impede adequate dietary intake. Key factors include opportunistic infections and co-morbid conditions, occurrence of diarrhea, symptoms of gastrointestinal distress or malabsorption and functional status (HRSA, 2004).

Dietary assessment examines the subjects' dietary intake patterns and evaluates the factors influencing ability to achieve an adequate diet, such as nausea, anorexia, infection, food intolerances, or altered taste and smell.

2.3 Nutrition education and counseling

Nutrition counseling is integral to comprehensive care of PLWHA (Piwoz 2004) and has demonstrated effectiveness in reversal of weight loss in PLWHA (Nerad *et al*, 2003). It

includes counseling PLWHA to help mitigate the effects of HIV and AIDS-related symptoms such as diarrhea, nausea, vomiting, anemia, oral thrush, loss of appetite and fever (FANTA 2004), and assisting them to improve food intake and maintain weight during asymptomatic HIV infection. Nutrition counseling (with regular follow-up) is also recommended to provide information on whether drugs should be taken with or without food, and to monitor changes in nutritional status and body composition after treatment is initiated (FANTA 2004). Nutrition education and dietary counseling are simple yet effective means of stabilizing or increasing body weight in PLWHA and positively affect their attitude to recommended dietary modifications and thus improved nutritional status (Niekerk *et al*, 2000). It is therefore acknowledged that if PLWHA through nutritional counseling are exposed to knowledge of the interaction between nutrition and diseases focusing on HIV/AIDS, it is expected to positively affect their attitude to recommended dietary modifications and thus improve their nutritional status.

2.4 Food security and assistance

Household food security of PLWHA can be compromised due to the debilitating effect of the disease if the household heads become incapacitated and therefore with no income, the households' financial independence is lost resulting sale to of household property to offset medical bills leading to poverty. In Kenya, it has been reported that between 49 and 78% of a family's income is lost when one of their own die of HIV/AIDS (Kenya National Strategic Plan, 2000). Therefore, in some instances, households may require food assistance/aid to prevent malnutrition and mortality among PLWHA and other household

members. Purpose of the food aid is to supplement daily nutritional requirements and support nutritional management of symptoms of opportunistic infections.

On-site feeding is the preferred form of food aid provision (Rogers and Coates, 2002). In this case, the food is prepared in a central place and the beneficiaries consume the meal or snack at the site. This ensures that the food reaches the targeted beneficiary. However, due to prohibitively high logistical expenses required to undertake onsite feeding, take-home food-by-prescription (FBP) is a more preferable method. FBP is the provision of food based on individual assessment. It is meant to halt and reverse the impact of malnutrition on the patient. The food is packaged in small quantities for one to take home, where it is consumed as prescribed. FBP is meant to reduce the administrative costs and resources required for on-site feeding. This was the form adopted by the study.

2.5 Health-related quality of life

According to the World Health Organization (WHO), quality of life is an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns and their fulfillment or not (WHOQOL Group, 1993). Health-related quality of life on the other hand refers to the true impact of health and disease on quality of life. In the context of healthcare, the term HRQOL is preferred over quality of life because the focus is on health. HRQOL includes several dimensions of health directly experienced by PLWHA including: physical functioning, social functioning, role functioning, psychological functioning and socio-

economic environment. It consists of the ability to perform daily activities, ranging from the ability to obtain food, to its preparation and the ability to consume it as well as undertaking activities such as walking and gainful work, or the inability or lack thereof, because of health all of which influence well-being.

2.6 Importance of measuring HRQOL and its change in PLWHA

Researchers have realized that traditional outcome measures are of little interest to the patient and that some form of ‘real life’ outcome measure is required in the current health climate (Dijkers, 1999). Although the success of the antiretroviral drugs (ARVs) in prolonging patients’ lives is seen as positive, physical distress and psychological pain remain a part of the illness (O’Neill and Alexander, 1997) as patients deal with the shock of the diagnosis and automatically switch to thoughts of impending death all of which decrease HRQOL in HIV positive patients (Wilson *et al*, 1997). HRQOL measurement in populations with HIV infection provides important information about prognosis and risk stratification that goes beyond the clinical variables (Cunningham *et al*, 2005).

2.7 Components of health related quality of life

2.7.1 Physical functioning

Studies have indicated physical functioning as a major indicator of overall physical HRQOL (Berzon *et al*, 1998). Recognizing the importance of physical functioning and bodily pain can help direct treatment to these problems and enable clinicians to improve HRQOL itself. Furthermore, these HRQOL deficits in particular may be reflective of

underlying risk or illness severity that is not fully measured by laboratory tests. In general, physical activity is categorized in levels of intensity from light to moderate to vigorous (PAHO, 2002) and more specifically in climbing stairs, walking, bending or kneeling, and in daily activities such as washing, bathing or dressing.

Physical health functioning inability has been found to be the most important problem faced by PLWHA. In its advanced stages, HIV/AIDS has the effect of limiting the individual's ability to perform physical activity and exercise due to wasting, increased presence of opportunistic infections (OIs) and lack of energy. The affected households may face costs related to reduced levels of work output and loss of productivity that result from inability to work or a change of employment and consequently loss of income (Shisana and Letlape, 2004) thus pushing them deeper into poverty. Cost of treating OIs in patients also increases.

PLWHA can reap some of the same benefits of exercise as the general population (Stringer *et al*, 1998). Exercise training is an inexpensive and efficacious strategy for improving HRQOL in PLWHA (Mutimura *et al*, 2008). It provides many health benefits, ranging from improving appetite, nutritional status in HIV/AIDS (Roubenoff *et al*, 1999) and improved quality of life (Stringer *et al*, 1998). It also helps in improving blood circulation, relieving constipation, improving the intestinal transit time, lowering cholesterol levels hence decreasing the risk of heart disease, stroke and diabetes, reducing mental depression and eliminating excess fat. Exercises reduce stress and anxiety thus reducing morbidity and

mortality from mental health disorders hence improved HRQOL. A regular moderate-intensity physical activity such as walking, climbing stairs, performing house chores or gardening for 30 minutes every day are recommended for acquiring and maintaining moderate fitness (Blair *et al*, 1996).

2.7.2 Role functioning

HIV/AIDS causes a debilitating condition whereby PLWHA are not able to perform activities of daily living including household chores due to morbidity, failing strength and lack of energy. Those who suffer from intense symptoms, pain, or fatigue are more likely to be limited in their daily role-functioning. Moreover, they are limited in their ability to perform energy-demanding activities such as climbing stairs, walking for long distances and performing other strenuous activities. Malnutrition further complicates this by compromising the immune system resulting in increased susceptibility to severe illnesses and increased risk of PLWHA becoming bed-ridden.

2.7.3 Psychosocial functioning

Psychosocial health is an important factor in predicting the physical health and well-being of PLWHA. It assesses the patient's own thoughts about body image and appearance, negative feelings, self-esteem and personal beliefs and includes feelings of emotional distress, depression and anxiety. The psychological consequences of HIV infection are diverse including feelings of sadness, despair and confusion (Kalichman, 1995). The despair of having a stigmatizing disease leads to depression, which is a state that affects the

mind, emotions and body creating lethargy, anxiety, irritability, insomnia, displeasure and hopelessness that lasts for weeks, months, or even longer. It involves the emotions of sadness and grief often accompanied by anger and fear often associated with reduced immunity (Schleifer *et al*, 1989). It affects nearly 37% of PLWHA (Gonzalez, 2001) with severity varying for individual persons over time. Depression is probably the most common psychological disorder with WHO predicting that by 2020, depression will be the second biggest health problem world-wide, behind heart disease (WHO, 2001). Prolonged periods of anxiety and tension can cause mental depression.

Depression impacts on all aspects of everyday life; including appetite (Kerstin and Fägerskiöld, 2003) and sleep (Angelino and Treisman, 2001). Two main types of depression have been identified namely major depression (more severe, short-lasting) and the dysthymia (less severe, longer-lasting). A combination of counseling and exercise has been suggested to reduce depressive symptoms. While the benefits of counseling have long been understood, attention is now being given to the positive effect of exercise as well. Exercise not only keeps the body physically and mentally fit, but also provides recreation and mental relaxation. It tones up the body, provides a feeling of accomplishment, and reduces the sense of helplessness. Exercise increases blood flow hence more oxygen to the blood cells thus releasing natural endorphins which are linked to mood enhancement, increased metabolism, higher energy levels and decreased stress.

Self-esteem reflects overall self-appraisal of one's own worth. Changes in physical appearance including wasting have a negative impact on self esteem. (Register, 1989). As HIV/AIDS progresses, the body undergoes changes including lipodystrophy, wasting and visible signs of OIs thus reduced self confidence (Visintini and Bagnato, 1995). Lipodystrophy, a syndrome characterized by loss of subcutaneous fat from limbs and face and deposition of excess fat in the upper back, trunk and neck is usually associated with HIV/AIDS and ARV drugs. These changes in body shape are disfiguring and could have significant effects on physical appearance and functioning, which can negatively affect self-perceived body image (Martinez *et al*, 2005).

Stigma and discrimination have a great impact on self-esteem. They cause an individual to seem undesirable and rejected by others. The associated stigma due to wasting remains a major impediment in the fight against HIV/AIDS (Dangerfield *et al*, 1994) and It is aggravated by signs and symptoms of HIV related OIs (Hedge, 1991). Discriminatory practices towards PLWHA such as pre-employment screening, denial and termination of employment (Omangi, 1997) have been reported and are likely to lead to stress and depression. This situation discourages PLWHA from disclosing their status. Disclosure has been identified as a major psychological stressor in PLWHA (Semple *et al*, 1993) has been a major hurdle in the fight against stigma and discrimination. However, disclosure to friends is becoming significantly more common than to family members (Kalichman *et al*, 2003).

Sleep an attribute of psychosocial health is the natural state of bodily rest observed in all animals. The duration of sleep differs among individuals but the optimum is thought to be between 6-8 hours (Ferrie *et al*, 2007). Decrease (≤ 5 hours) and increase (> 8 hours) in sleep duration is associated with an increase in mortality via effects on cardiovascular and non-cardiovascular death respectively (Ferrie *et al*, 2007). Sleep disturbances including difficulty in both falling and staying asleep can be caused by psychological factors among them stress, anxiety and depression. They can also be caused by physical symptoms such pain, diarrhea, fever, night sweats and cough.

2.7.4 Morbidity

PLWHA are faced with a myriad of problems including signs and symptoms of OIs such as diarrhoea, night sweats, anorexia, nausea/vomiting, fever, fatigue, body pain and cough. Chronic diseases such as diabetes and hypertension are also a common reason for disability and early death in PLWHA, and have been shown to lead to worsening of their HRQOL (Tuominen *et al*, 2007). Even with the advent of ART, OIs continue to cause morbidity and mortality in PLWHA throughout the world thus compromising the QOL of patients. Studies have shown that as HIV/AIDS symptoms develop, the HRQOL for the individual decreases (Lorenz *et al*, 2006), with others identifying emotional well being and physical functioning (Globe *et al*, 1996), ability to perform social roles (Crystal, *et al*, 2000) and physical symptoms (Cunningham *et al*, 1998) as the factors most responsible for HRQOL.

Malabsorption is a common manifestation of HIV infection and may be secondary to lactose intolerance or gastrointestinal infections (Keithley *et al*, 1998). It results when HIV damages the small intestine and alters the healthy bacteria of the digestive system thus causing diarrhoea. HIV related diarrhoea is an important cause of morbidity and mortality in HIV infection (Sabin *et al*, 1999). About 90% of PLWHA develop, at some point, diarrhoea. This can lead to dehydration, significant weight loss, malnutrition, and malabsorption, and can result in increased mortality. Diarrhoea may also result in significant deterioration in social activity, activities of daily living, energy, and general health (Douaihy *et al*, 2001). Diarrhoea in HIV infection can be caused by infection of the immune system within the gut or by contamination of food because of poor food hygiene.

Nausea and vomiting can be an important problem for people living with HIV/AIDS. According to the Webster dictionary, nausea is “stomach distress with distaste for food and an urge to vomit”. It is often due to side effects of medications or symptoms of an underlying illness. Nausea reduces appetite and can be caused by certain factors including foods, infections, stress and as a side effect of ARV drugs (FAO, 2002).

Fatigue is a lack of energy, exhaustion and prolonged tiredness. It occurs in most patients with HIV infection and AIDS (Groopman, 1998) and may be due to depression, anemia, pulmonary impairment, hormonal deficiencies and nutritional deficiencies. It impacts significantly on the psychological well-being and quality of life of PLWHA (Rose *et al*,

1998). Fatigue may also be associated with decreased caloric intake due to lack of energy to eat or prepare food.

Sweating is a natural body function and is a means of evaporative cooling. However, it is undesirable when it occurs consistently night after night, leaving the affected person wet and shivering. Night sweats, also known as hyperhidrosis (profuse sweating that is not related to exercise) may present as a symptom of HIV infection or a sign of another infection such as tuberculosis (TB), histoplasmosis, idiopathic hyperhidrosis (a condition in which the body chronically produces too much sweat without any identifiable medical cause) or medications.

Body pain impairs HRQOL substantially in PLWHA. Studies have shown that pain affects most domains of QOL, primarily physical and emotional functioning (David, 2001). Pain in HIV/AIDS may be due to tissue injury as a result of inflammation (including autoimmune responses), infections or neoplasia. Nearly half of the pain experienced by PLWHA is neuropathic, reflecting injury to the central nervous system from direct pathogen infection, or neurotoxic effects of drug therapy (Carr, 2009). The effect of pain depends on the extent, duration, acuteness, intensity and meaning of the pain as well as on the underlying disease and the individual's characteristics.

Despite the usefulness of ARVs in prolonging life, long-term ART may cause various adverse effects affecting the patient's quality of life (Cholewinska, 2005). Some adverse

effects of HAART affecting QOL include nausea and vomiting, hepatotoxicity, rash, neuropathy and lipodystrophy. On the contrary, use of ART may improve the QOL of patients by reducing the virulence of HIV hence improved immunity, less OIs and reduced disability.

2.8 Measuring HRQOL

While there is increasing evidence for the value of HRQOL assessment, one of the most difficult tasks that remains is its quantification. HRQOL is subjective and can prove a challenge to measure. Some of its components such as psychosocial aspects cannot be directly observed. Majority of researchers recognize that when measuring quality of life, it is important to focus very clearly on specific domains important to the disease being assessed. The inherent vagueness in general questioning could lead to difficulties in interpretation. Disease specific HRQOL questionnaires are better able to detect small changes in quality of life.

Anthropometric measurements reflect both health and nutritional status and predict performance, health and survival. They are objective measurements of weight, height, body mass index, MUAC, TSFT, body fat and waist to hip ratio. These measures are compared to reference standards to assess weight status and the risk for various diseases. Several researchers have suggested the use of anthropometric measures to assess body composition (Ludy *et al*, 2005).

BMI is the most widely used anthropometric indicator for assessment of adult nutrition status (Lee and Nieman, 2003) and has been established as a predictor for mortality and progression of HIV (Malvy *et al*, 2001). BMI measures the body's weight relative to height and is therefore a good tool for assessing body composition. It is a better predictor of disease risk than body weight alone and is used to determine the degree of wasting or obesity on subjects. Currently WHO recommends a BMI cut off of $<18.5 \text{ kg/m}^2$ as underweight (WHO, 1995). BMI is widely used as a practical measure for chronic energy deficiency (CED), defined as a 'steady' underweight in which an individual is in energy balance irrespective of a loss in body weight or body energy stores (Shetty *et al*, 1994). According to the WHO classification for adult malnutrition (WHO, 1995), BMI can be categorized on the level of chronic energy deficiency (CED). CED III = $\text{BMI} < 16 \text{ kg/m}^2$, CED II = $16 - 16.9 \text{ kg/m}^2$, CED I = $17 - 18.4 \text{ kg/m}^2$ and marginal BMI = $18.5 - 24.9 \text{ kg/m}^2$. CED is caused by inadequate intake of energy accompanied by high level of physical activities and infections (Shetty *et al*, 1994). CED has been associated with reduced work capacity (Durnin 1994), reduced performance and productivity (Kennedy and Garcia, 1994) and increased morbidity due to suppressed immune function (Shetty and James, 1994). It is worth noting that other methods for measuring body composition exist including mid upper arm circumference (MUAC) and body fat.

MUAC is the circumference of the left upper arm, measured at the mid-point between the tip of the shoulder and the tip of the elbow (olecranon process and the acromium). The measurement of MUAC is used as a screening method for underweight especially in bed

ridden patients, during pregnancy or as an additional criterion with BMI to identify the preferential loss of peripheral tissue, fat stores, protein (Ferro-luzzi and James, 1996). MUAC as a screening tool has been proposed as an alternative to BMI particularly in emergency situations (Ismail and Manandhar, 1999) and may also be used to predict mortality (Briend and Zimick, 1986). James *et al* (1994) suggested and used a MUAC cut-off of below 23 cm for men and 22 cm for women to indicate undernutrition. The difference in MUAC between the genders is due to the fact that men have more muscle than women. However, without separating the genders, Garrow (1993) suggested the categorization of MUAC on the basis of CED. CED III = < 16cm, CED II = 16 – 16.9cm, CED I = 17 – 18.4cm, CED 0 = 18.5 – 22.9cm. Nevertheless, MUAC has its limitations as an index of undernutrition since it does not differentiate acute from chronic energy deficiency (Collins, 1996). Therefore, it cannot be used as a follow up indicator to assess malnutrition. Consequently, interpretation of MUAC should be done with caution since it may be affected by the redistribution of subcutaneous fat towards central areas of the body especially during ageing.

Total body fat consists of storage and essential fats (Corbin *et al*, 2004). Storage fat consists of fat accumulation in adipose tissue, part of which protects internal organs in the chest and abdomen. Essential fat is necessary for temperature regulation, shock absorption, regulation of essential nutrients (vitamins A, D, E and K), maintenance of life and reproductive function and is sometimes broken down to release energy (Corbin *et al*, 2004). Any fat above the essential is referred to as nonessential fat. Body fat cut off percentages of

24% and 36% to indicate 'overfat' in men and women respectively have been used in several studies (Taylor *et al*, 2002). Other literature have suggested the required body fat levels as 10-20% for men and 17-28% for women (Corbin *et al*, 2004). Studies have shown that patients with body fat of <12% have a death hazard ratio (HR) 4 times that of patients with body fat content between 24% and 36% (Kamyar *et al*, 2006). Bioelectric impedance analysis (BIA) through measurement of body fat can be used to assess body composition (Keiserman *et al*, 1997). BIA is a simple and quick method for determining the lean body mass or body composition of an individual. It determines the electrical impedance of body tissues, which provides an estimate of total body water. BIA is based on the principle that the resistance to an applied electric current is inversely related to the amount of fat-free mass within the body. The impedance measurement reflects the degree of resistance to the flow of current in the body, water being a good conductor and fat a bad conductor. It is measured when a very small electrical current carried by water and fluids is passed through the body. Impedance is greatest in fat tissue, which contains only 10-20% water, while fat-free mass, which contains 70-75% water, allows the signal to pass much more easily.

All the assessment methods described above have direct or indirect effects on HRQOL. Nevertheless, it is worth noting that the responsiveness of any QOL scale depends on the patients' initial health status. Therefore, in instances where a patient is very unwell, the reported initial QOL may be so low such that any further deterioration upon future assessment may be difficult to detect.

CHAPTER THREE

METHODOLOGY

3.1 Study site

Naivasha District Hospital comprehensive care centre (CCC) was the preferred site for data collection. The study site was purposively selected as part of a larger study titled ‘Randomized controlled evaluation of the impact of food supplements on malnourished HIV-infected adult ART clients and malnourished HIV-infected pre-ART adults in Kenya’, (SSC No. 1023) that was being implemented by KEMRI. Naivasha town is the administrative headquarters of Naivasha District approximately 80 km North-West of Nairobi with a population of 32,222 (CBS, 2003). It is a cosmopolitan urban residential town with the main industry being horticultural farming of flower, vegetables, fruits and wheat. Naivasha is also a popular tourist destination with Hell's Gate National Park, Longonot National Park and Mount Longonot being tourist attractions. It is surrounded by the Aberdare mountain range to the East, Mount Longonot to the South, the Mau Escarpment to the West and to the North mount Eburru. Naivasha District Hospital is a public facility in Naivasha town and recruits 50-60 patients per month.

3.2 Study population

The study population comprised HIV+ adults attending the CCC. ARVs were provided to HIV+ adults who met the WHO Stage IV disease criteria, or who met the WHO Stage III disease criteria and have a CD4 count < 350 cells/mm³. ART is a fixed-dose combination of three antiretroviral drugs; in Kenya the first-line ART is Stavudine, Lamivudine, and either

Efavirenz or Nevirapine (NASCOP, 2005). Pre-ART clients are HIV+ adults who are either asymptomatic or symptomatic (CD4 of 250-500 350 cells/mm³) and attending treatment clinics for opportunistic infections but not yet eligible for ART according to the WHO guidelines (WHO, 2003) and the Kenya National ART guidelines (NASCOP, 2005).

3.3 Sample size estimation

The following formula was used for sample size computation (Wang *et al*, 2008):

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

Where:

Z = the Z-value attributed to σ and to 1- β . 1- β = the power of the study (80%), σ = significant level (at 0.05)

($\mu_1 - \mu_2$ = the expected difference (after food supplementation) in BMI that can be detected by the sample population and claimed to be the effect of supplementation - 0.6kg/m²).

$$n = \frac{2 \times \text{Stdev}^2 (1.96 + 0.842)^2}{0.6^2}$$

n = 98 (per group) add 10% due to loss to follow up N= 110 per group

3.3.1 Inclusion criteria

- HIV+ adults (18 yrs and above) with BMI > 14 and < 18.5 kg/m² for ART clients
- HIV+ adults (18 yrs and above) with BMI > 14 and < 20 kg/m² for Pre-ART clients
- Beginning or have begun Cotrimoxazole prophylaxis within the past 4 months
- Non pregnant, non lactating women
- Those not already receiving another food supplement

3.3.2 Exclusion criteria

- Pregnant and lactating women and women who become pregnant during the study
- Subjects already receiving another food supplement
- Subjects who begun Cotrimoxazole prophylaxis more than 4 months

3.4 Study design

An interventional two-arm comparative study design with 3 months follow up was adopted. One group was provided with the food supplement and nutrition counseling (FS + NC) while the other received nutrition counseling alone (NC).

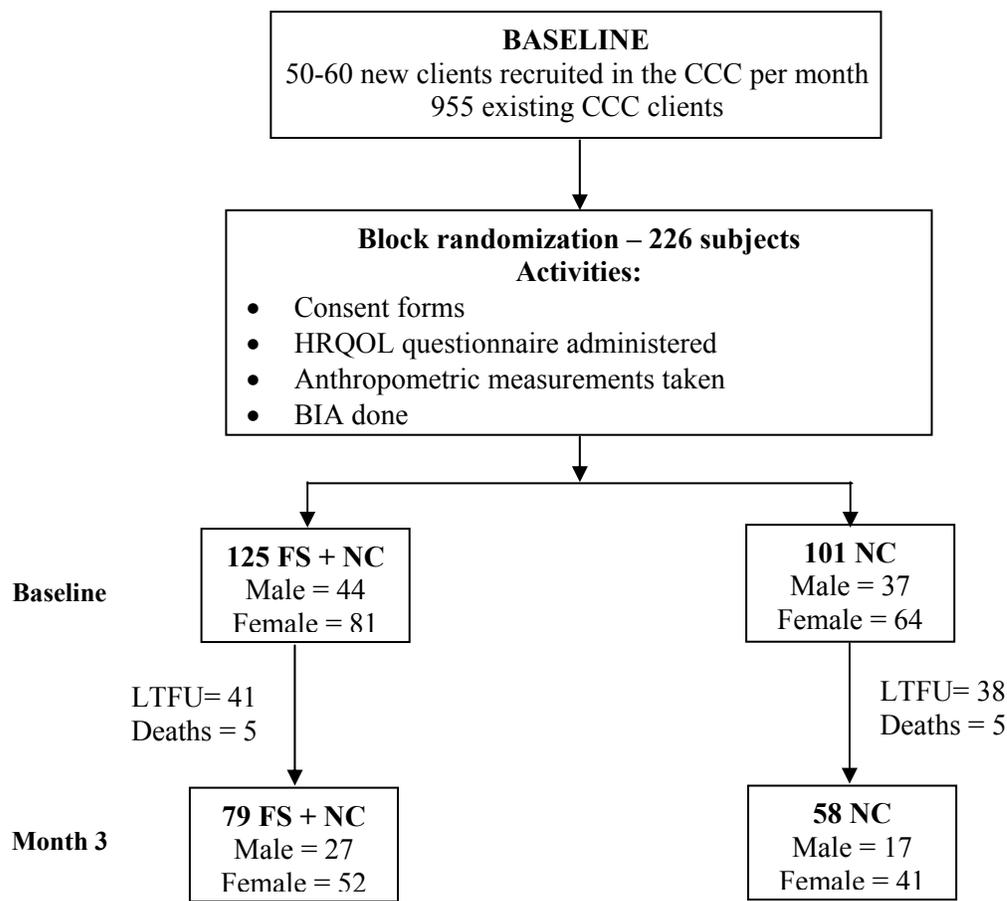


Figure 3.1: Study design and subjects follow up

FS + NC group: 300 g/day of fortified blended flour (Foundation™) and nutrition counseling for 3 months.

NC group: Nutrition counseling alone for 3 months

Food supplement

The food supplement provided was Foundation plus; a mixture of maize and soya flour, sugar, palm oil and fortified with multiple micronutrients (Appendix 1) produced by Insta Foods Kenya Ltd. The eligible clients received FBF prescriptions aimed at providing about 45% of clients' daily energy requirements, 50% to 78% of protein requirements, and about 1 Recommended Daily Allowance of micronutrients. The recipient subjects were provided with a month's supply (9 kg) of the food and instructed to consume 300g of the food supplement daily. They also received instructions on preparation of porridge (*uji*). The food supplement was distributed monthly at the CCC within the study sites. During counseling, emphasis was put to the effect that the food supplement was like medicine hence not to be shared. On subsequent visit, the number of packets remaining was recorded and counterchecked with the expected number and subjects counseled accordingly in case of discrepancies.

Nutrition counseling

All subjects received nutritional counseling carried out by a trained nutritionist attached to the CCC using the Ministry of Health (MoH) counseling card and wall charts. Components of the nutrition counseling undertaken included the following:

- i. Benefits of good nutrition
- ii. Need for increased nutrient intake in HIV/AIDS
- iii. Dietary recommendation
- iv. Importance of adequate water intake
- v. Nutritional management of HIV related signs and symptoms
- vi. Food drug interaction in the context of HIV/AIDS
- vii. Prevention of communicable opportunistic infections

The effect of nutrition counseling was measured using the following indicators: frequency of eating meals and snacks, water treatment and consumption, change in personal habits (smoking and drinking alcohol), reduced incidences of symptom burden and performance of exercises.

3.5 Sampling method

The study utilized a complete random block design in the allocation of subjects to various treatment interventions. Clients from each arm were recruited into blocks of 10 clients. Randomization was done within blocks to allocate patients to one or the other treatment intervention within each block. A random numbered assignment of 10 numbers was generated, and after completing the informed consent process each patient was required to collect a card number available in an opaque sealed envelope, which was matched to one of the two treatments hence 5 clients on food supplement and nutritional counseling and 5 on nutritional counseling alone.

3.6 Data collection

Both qualitative and quantitative data were collected using a structured questionnaire administered by trained personnel at the CCC. Data collected included anthropometry (weight, height, MUAC and body fat), socio-demographic and socio-economic characteristics, physical and psychosocial functioning, morbidity and general health status. The questionnaire was pre-tested on a trial run of 5 clients to ensure the procedures and logistic could be implemented as planned. Data was collected at two time points; that is at baseline and after 3 months of subjects' follow-up. To achieve accuracy, anthropometric measurements were undertaken by the same person each time in duplicate. In case of drop-outs, efforts were made through community health workers, use of subjects contact phone numbers and physical tracing to determine the reason for drop-out.

3.6.1 Nutritional status

i. Measurement of Weight

Weight measurement was done in duplicate and the average recorded in kilograms to the nearest 0.1kg. This was done using a leveled Salter scale according to WHO standardized procedures (WHO, 1995). The individual was required to stand still, wearing minimal clothing, barefoot and unsupported on the scale. The scale was periodically calibrated using a known weight (20kg).

ii. Measurement of Height

Height measurement was done in duplicate and the average recorded. Standing height was recorded to the nearest 0.1 centimeter (cm), using a measuring board. The individual was measured standing barefoot or in thin socks and wearing minimal clothing, body against a vertical board (WHO, 1995). The individual was required to stand heels together, arms hanging freely by the sides, and head, back, buttocks, heels in contact with the vertical board and the head positioned so that the eyes are looking straight. A horizontal headboard was then lowered until it firmly touched the top of the head.

iii. Body mass index

BMI was used to determine the degree of wasting on the subjects and was calculated by taking an individual's weight in kilograms and dividing it by subject's height in metres squared (kg/m^2).

iv. Measurement of mid upper arm circumference

Subjects were requested to remove or fold any clothing that reach the wrist. With the left arm bent at the elbow and hand flat against his stomach, the distance between the tip of the back of the elbow (acromium) and top of the shoulder (olecranon) was identified and the midpoint marked. A MUAC tape was then wrapped loosely around the arm at the midpoint and the measurement recorded to the nearest cm. This was done in duplicate and the average recorded.

v. Measurement of body fat

Body fat percentage was measured using the BIA technique (Bodystat[®] 1500 machine). This method measures body composition by sending a low, safe electrical current (200 mA) from dry batteries through the body. Clients were instructed to empty their bladder, requested to remove their shoes and any metallic objects on them and lie on a couch. After cleaning the area with cotton swabs and allowing drying, two electrodes were placed on the back of the wrist joint and two in front of the ankle joint on the same side of the body. The current passes freely through the fluids contained in muscle tissue, but encounters resistance when it passes through fat tissue. The device automatically computed the impedance taking into consideration the age, gender, height, weight and level of activity of the individual and the results displayed on the screen. This resistance of the fat tissue to the current is termed 'bioelectrical impedance'.

vi. Assessment of health status

Health status of subjects was categorized using the WHO criteria for clinical staging of HIV/AIDS (Appendix 2). Therefore, subjects were deemed to have excellent, good, fair or poor health depending on the presence or absence of HIV related signs and symptoms.

3.6.2 Health-related Quality of Life

HRQOL was assessed using a health-related quality of life questionnaire, an adaptation from Healthy Days Measure questions, from the Centers for Disease Control (CDC) – CDC HRQOL-14 and the Short Form-36 (SF-36). Measures of HRQOL assessed included ability

to perform physical activities and exercises, stigma and discrimination, sleep patterns, negative feelings (guilt, despair, blue and anger), health status and morbidity events. Questionnaires were used to collect data on demographic, socio-economic characteristics, anthropometry (Appendix 3), physical and psychosocial functioning (Appendix 4), morbidity events Appendix 5), food consumption habits and lifestyle (Appendix 6).

3.7 Measures

- **Malnutrition**

Undernutrition was classified on the levels of CED using both BMI and MUAC. BMI: 18.5-20 kg/m² (Marginal), 17-18.4 kg/m² (mild), 16-16.9 kg/m² (moderate) and <16 kg/m² (severe).

MUAC: ≥ 23 cm (Normal), 18.5-22.9 cm (at risk), 17-18.4 cm (mild), 16-16.9 cm (moderate), <16 cm (severe).

- **Health status**

Health status was classified using the WHO criteria for clinical staging of HIV/AIDS (Appendix 2) and categorized as excellent, good, fair or poor health depending on the presence or absence of HIV related signs and symptoms.

- **Meal**

Food routinely eaten at a more or less fixed times, especially breakfast, lunch and supper.

- **Snack**

A light food or drink that is readily available, eaten without much preparation and usually taken in between meals.

- **Symptom burden**

A set of 16 signs and symptoms were used to calculate the burden. Presence of any of the symptoms was given a value of 1 while absence was considered to be 0.

- **Sleep**

Optimum sleep duration was regarded as being 6-8 hours (Ferrie *et al*, 2007)

- **Physical activity**

Limited meant unable to perform activities while not limited meant able to perform activities with relative ease.

3.8 Data management and analysis

3.8.1 Data entry and validation

Questionnaires were checked for accuracy and completeness by the investigator. This was to ensure that all questions had been answered. The data collected was coded and entered using the statistical package for the social sciences (SPSS) software for Windows (SPSS Version 11.5). Validation was carried out in SPSS by generating frequency outputs and by

visual inspection of the questionnaires incase conspicuous anomalies were detected. Data was stored using flash disk, floppy disk and as hard copies.

3.8.2 Data analysis and presentation

Effect of food and nutrition counseling were established after comparison of baseline and follow up data within each arm of the study. Data analysis involved descriptive statistics, student's t-test for normally distributed data, Mann-Whitney U-test for skewed continuous data. Central measures of tendency used were means for normal distributed data and medians for skewed data. Chi square was used for categorical data to show association. Regression analysis was used to provide an insight into the relationship between BMI and MUAC under disease condition.

Nutritional outcome measures

Nutritional outcome measures included weight, height, BMI, MUAC and body fat. Central measures of tendency were used to establish the distribution. Student's t-test was applied in establishing the mean difference between the groups. Specific cut off points for BMI and MUAC were used based on gender differences and in categorizing degree of malnutrition. BMI was correlated with HRQOL measures to establish the level of association.

Non-nutritional outcome measures

Non-nutritional outcome measures included health status, morbidity events, performance of physical activity, sleep, stress and negative feelings. Categorical measures were tested for

association using the Chi square. Mean (SD) was used for continuous data and the student's t-test for differences in means between the groups.

3.9 Ethical consideration

Approval for scientific and ethical issues was granted by the Scientific Steering Committee and Ethical Review Committee respectively. Subjects were required to give consent to participate in the study by signing a consent form (Appendix 7). However, subjects who refused to participate in the study still benefited from ART and treatment for OIs. Subjects in the nutrition counseling group whose nutritional status deteriorated to BMI $<14\text{kg/m}^2$ were consequently put in the food group. Subjects from the pre-ART group who met the conditions for ARV during the study period were provided with the drugs. Permission to undertake the study in the various health facilities was sought from the provincial and respective health facility heads.

3.10 Expected application of the results

These results are expected to inform policy makers and programmers on the importance of health-related quality of life of PLWHA. They are also expected to emphasize the importance of food supplementation in improving not only the nutrition status of undernourished PLWHA but their well-being as well.

3.11 Limitations of the study

There is no standard tool for assessing HRQOL in Kenya. Available questionnaires such as the WHOQOL and SF-36 were adapted to specifically target the study population.

On commencement of data collection, it was realized that the available tool was not capturing adequate data. Hence, an additional set of questions (Appendix 6) were formulated and administered on a sub population of the main study subjects. The additional data included the following HRQOL measures:

- Food and snacks intake
- Water treatment and consumption
- Stigma and discrimination
- Depression and self esteem
- Duration of sleep

Follow up of defaulters was a challenge. These clients were physically traced by community health workers and use of mobile phones after which their family, relatives or community health workers request to bring the clients to the hospital not only for study purposes but for treatment as well.

Clients were in some instances asked to recall events that occurred 1 month prior to recruitment. Some subjects could not recall some events in the period.

Collection of data was affected by the post election violence witnessed across the country. Client flow to the health facilities reduced drastically due to relocation and displacement. Some study staff had to physically relocate to other regions. Overall defaulter rate was 39.8%.

The take-home supplementary ration provided to the subjects in the FS + NC group was not a family ration. Financial constraints could however not permit for it in this study. Therefore, there was the possibility of subjects sharing the food supplement with other family members or neighbours hence leakage which could have affected the study outcome.

CHAPTER FOUR

RESULTS

4.1 Cohort Characteristics

A total of 226 subjects were recruited into the study. 55.3% were randomized into the Food supplemented + Nutrition counseling (FS + NC) group and 44.7% in the Nutrition counseling alone (NC) group. There was equal distribution of ART and Pre-ART subjects within the intervention groups. 50.4% of subjects in the FS + NC group were on ART compared to 49.5% in the NC group.

4.2 Socio-demographic characteristics

Subjects in both groups were of comparable age. Overall, mean age was 35.1 ± 8.4 years. Men were significantly older than women [36.7 ± 8.2) vs. 32 (34.2 ± 8.4) respectively; $P = 0.029$] with a women : men ratio of 2:1 (Figure 4.1). More subjects in the NC group were married compared to the FS + NC group as presented in Table 1.

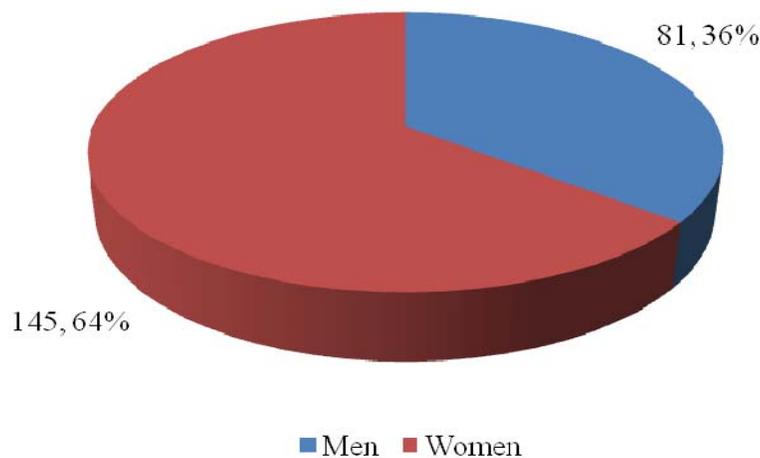


Figure 4.1: Sex of the subjects

Table 1: Socio-demographic characteristics of the cohort

Variable	FS + NC n=125	NC n=101	Overall N=226	P value
Mean (SD) age in years	34.6 (7.8)	35.7 (9.1)	35.1 (8.4)	0.309 [†]
Marital status	(%)	(%)	(%)	
Single	17 (13.6)	21 (20.8)	38 (16.8)	0.016*
Married/cohabiting	48 (38.4)	44 (43.6)	92 (40.7)	
Separated/divorced	41 (32.8)	15 (14.9)	56 (24.8)	
Widowed	19 (15.2)	21 (20.8)	40 (17.7)	
Median (min, max) number of household members	2 (1,10)	2 (1,7)	2 (1,10)	0.337 [#]

P value obtained by [†]Student's t-test, *Chi square test and [#]Mann-Whitney U test

4.3 Socio-economic characteristics

Both groups were comparable in the socioeconomic characteristics as shown in Table 2. 91.6% of subjects had received some form of education with majority having achieved primary education. 58.4% of subjects in both groups were employed (Figure 4.2) with 58.5% earning between Kshs 3,000 – 9,999 per month (Figure 4.3).

Table 2: Socio-economic characteristics of the cohort

Variable	FS + NC n=125	NC n=101	Overall N=226	P value
Highest education level	(%)	(%)	(%)	
None	7 (5.6)	12 (11.9)	19 (8.4)	0.157
Primary	82 (65.6)	62 (61.4)	144 (63.7)	
Secondary +	36 (28.8)	27 (26.7)	63 (27.8)	

P value obtained by Chi square test

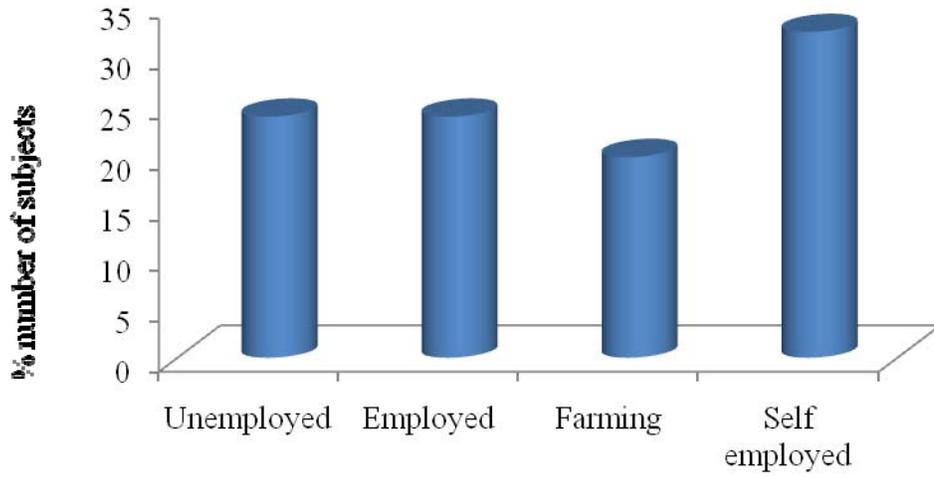


Figure 4.2: Employment status of the subjects

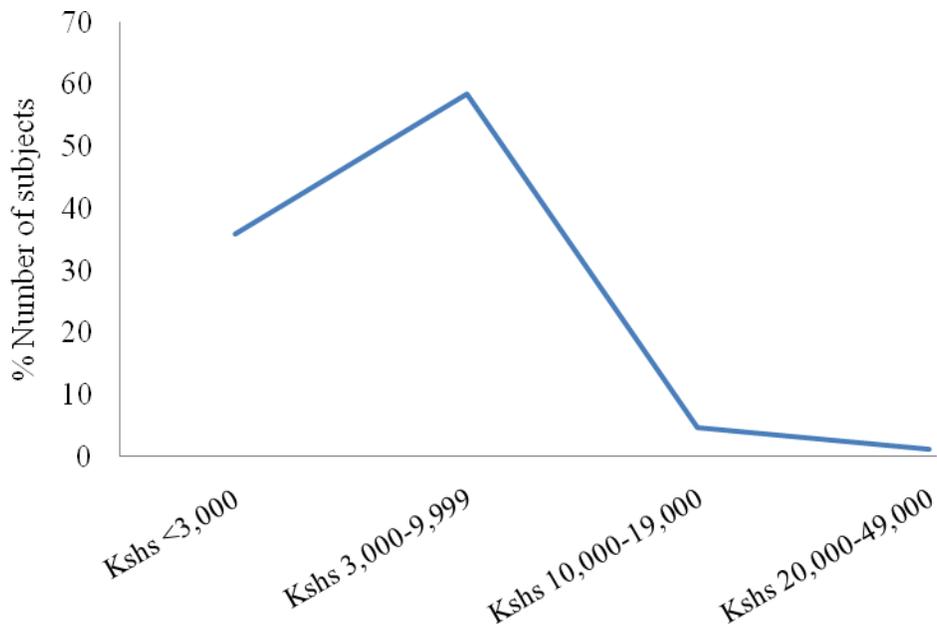


Figure 4.3: Distribution of subjects' monthly income

4.4 Baseline nutritional status

Baseline anthropometric measurements were comparable between the groups (Table 3).

Table 3: Baseline mean (SD) anthropometry and body fat percentage

	n	FS + NC	n	NC	<i>P</i> value
Weight (kg)	125	47.8 ± 6.9	101	47.4 ± 5.4	0.672
BMI (kg/m ²)	125	17.7 ± 1.6	101	17.5 ± 1.4	0.269
MUAC (cm)	118	21.4 ± 2.6	88	21.4 ± 2.6	0.143
Body fat (%)	112	22.9 ± 7.4	85	22.8 ± 6.6	0.75

P value obtained by student's t-test

Overall mean BMI in women was 17.3 (± 1.5) kg/m²) and 17.7 (± 1.5) kg/m²). Mean body fat percentage was greater in women (18.7 ± 6.4) than men (25.5 ± 6.7), *P* <0.01. Men in the FS + NC group had significantly higher weight (52.8 ± 5.5kgs) than their counterparts in the NC group {50.1 ± 5.3kgs, (*P* = 0.026)}.

BMI was significantly correlated with MUAC [*r* = 0.646; *P* < 0.01 (Table 4)]. A regression analysis (Figure 4.4) showed that for every 1 unit increase in BMI, MUAC increased by 0.37 (*R*² = 0.42; BMI = 9.53 + 0.37 * MUAC). BMI and body fat in the pooled data and within the groups did not establish a significant correlation.

Table 4: Regression analysis of anthropometric measures

Variables	B	SeB	t	<i>R</i> ²	df	<i>P</i>	95% CI	
							Lower	Upper
BMI* and MUAC	0.372	0.031	12.07	0.417	1	<0.01	0.312	0.433

* Dependable variable, B = regression coefficient, SeB = Standard error of B, df = degree of freedom

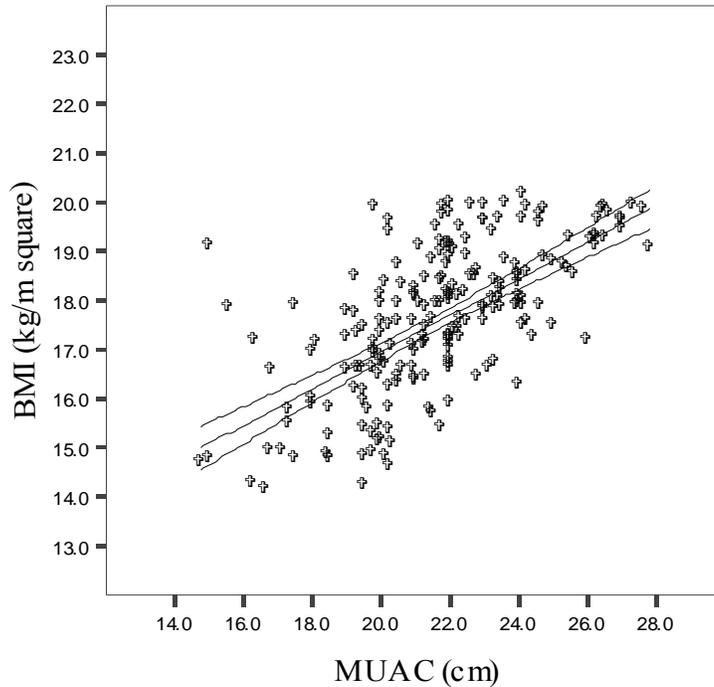


Figure 4.4: Distribution of BMI and MUAC at baseline

Chronic Energy Deficiency

Using BMI to categorize undernutrition, proportionately more subjects in the NC (74.3%) than the FS + NC group (67.2%) were undernourished. Of these subjects 18.4% and 15.8% in the FS + NC and NC groups were severely undernourished. Categorization of MUAC indicated that 64.4% and 56.8% of subjects in the FS + NC groups respectively were undernourished (Table 5). The distribution of the different grades of CED is presented in Appendix 8. No significant differences existed within and between the groups.

Table 5: Distribution of nutritional status using BMI categories

CED Levels		FS + NC n=125	NC n=101	<i>P</i> value
		(%)	(%)	
BMI categories	Undernourished	84 (67.2)	75 (74.3)	0.331
	Marginal	41 (32.8)	26 (25.7)	
		n=118	n=88	0.468
MUAC categories	Undernourished	76 (64.4)	50 (56.8)	
	Marginal	42 (35.6)	38 (43.2)	

P values obtained by Chi square test

4.5 Nutritional status after intervention

Comparison of anthropometric measurements within and between the groups

Subjects gained a mean weight of 3.3 kg \pm 4.3 ($P < 0.01$) irrespective of the intervention group after 3 months of follow up. The mean weight for subjects who gained weight was 4.7 kg \pm 3.5. The intervention also resulted in significant increase in BMI in both groups ($P < 0.01$). Body fat changes however did not achieve significance. Mean (SD) body fat percentage change was -0.5 (6) in the FS +NC group and -0.1 (7) in the NC group. No significant differences were elicited between the groups

In the FS + NC group, subjects gained a mean weight and BMI of 1 kg and 0.4 kg/m² respectively after the first, second and third months of follow up (Table 6). The mean Weight and BMI gain in both groups was greatest after 3 months of follow-up.

Table 6: Mean (SD) change in anthropometric measures

Variable	Group	Baseline and Month 1			Baseline and Month 2			Baseline and Month 3		
		n	Mean (SD) change	<i>P</i> value	n	Mean (SD) change	<i>P</i> value	n	Mean (SD) change	<i>P</i> Value
Weight (kg)	FS + NC	82	1.4 (2.3)	0.221	80	2.3 (3.3)	0.386	79	3.3 (4.2)	1.000
	NC	63	0.8 (3.4)		60	1.7 (3.9)		58	3.3 (4.3)	
BMI (kg/m ²)	FS + NC	82	0.5 (0.8)	0.161	80	0.9 (1.2)	0.296	79	1.3 (1.6)	0.711
	NC	63	0.3 (1.3)		60	0.6 (1.5)		58	1.2 (1.6)	

P values obtained by student's t-test

BMI response

The proportion of marginally malnourished subjects who had a BMI gain after the intervention was greater in the FS + NC group as compared to the NC group ($P = 0.048$)

Table 7.

Table 7: BMI responses after intervention

Group	n	Direction of change	Grades of undernutrition					
			Moderate to severe	Mild	Marginal	<i>P</i> value	<i>P</i> value	<i>P</i> value
FS + NC	79	Gain	13 (16.5)	25 (31.6)	26 (32.9)	0.901	0.513	0.048
NC	58	Gain	14 (24.1)	23 (39.7)	10 (17.2)			

P value obtained by Chi square test

Table 8 indicates that BMI was significantly correlated with MUAC in the FS + NC ($r = 0.686$; $P < 0.01$) and NC group ($r = 0.911$; $P < 0.01$). The regression analysis presented in Figure 4.5 established that for every 1 unit increase in BMI, MUAC increased by 0.56 (R^2

= 0.47; BMI = 6.36 + 0.56* MUAC) in the FS + NC and by 0.68 ($R^2 = 0.83$; BMI = 2.86 + 0.68* MUAC) in the NC group.

Table 8: Regression analysis of anthropometric measures

Variables	Groups	B	SeB	t	R^2	df	P	95% CI	
								Lower	Upper
BMI* and MUAC	FS + NC	0.558	0.067	8.27	0.47	1	<0.01	0.423	0.692
	NC	0.677	0.042	16.04	0.83	1	<0.01	0.592	0.761

* Dependable variable, B = regression coefficient, SeB = Standard error of B, df = degree of freedom

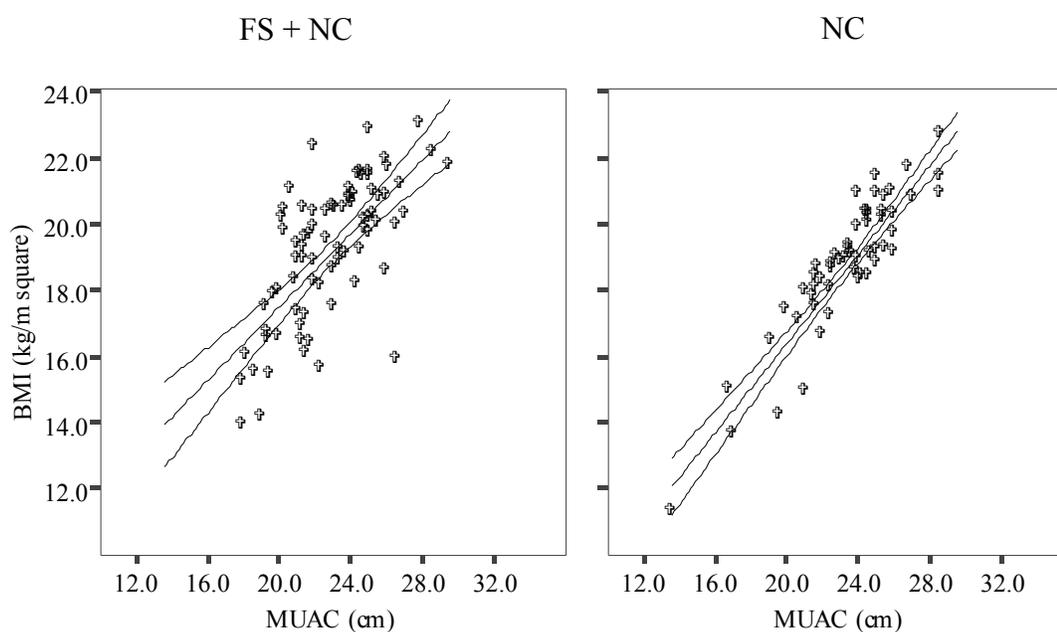


Figure 4.5: Distribution of BMI and MUAC after intervention

4.6 Baseline health related quality of life

4.6.1 Morbidity

Majority of respondents in the FS + NC (48.2%) and NC group (55.6%) self reported their health as being fair (HIV/AIDS clinical stage III). Only 4.5% in the FS + NC and 6.6% in the NC group reported having very good health (no signs and symptoms associated with HIV/AIDS) as illustrated in Figure 4.6. There existed no statistical significance group difference ($P = 0.405$).

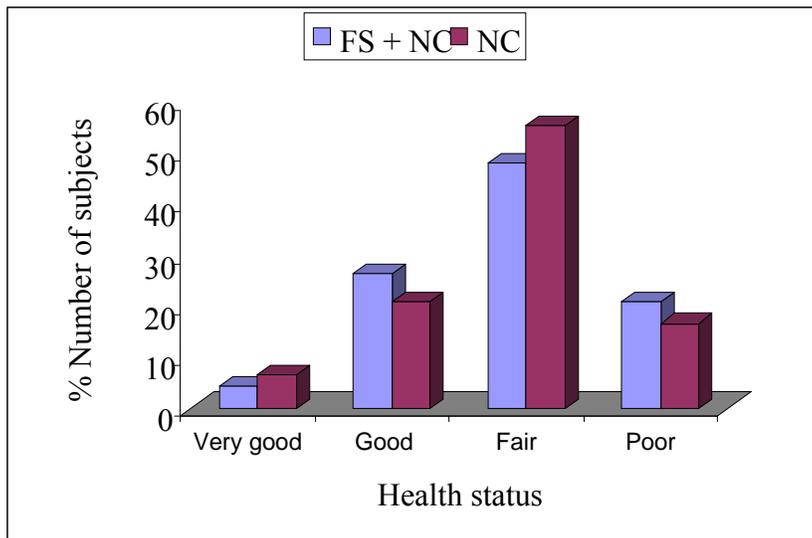


Figure 4.6: Baseline distribution of self reported health status

Sixteen signs and symptoms were considered in calculating the symptom burden. Overall mean symptom burden 12.2 ± 2.7 morbidity events (12.1 ± 2.8 in the FS + NC and 12.4 ± 2.5 in the NC groups). The commonly reported signs and symptoms were; poor appetite, fatigue, body pain and diarrhoea (56.8%, 51.5%, 18.4% and 12.6% respectively). There were no differences in signs and symptoms between the groups (Table 9). With regard to sex differences, fatigue was present in 52.6% and 50.8% of men and women respectively.

Table 9: Signs and symptoms experienced within the past Month

Sign and symptoms	FS + NC	NC	<i>P</i> value
	n=118	n=88	
	(%)	(%)	
Poor appetite	70 (59.3)	47 (53.4)	0.398
Fatigue	57 (48.3)	49 (55.7)	0.296
Nausea	48 (40.7)	25 (28.4)	0.069
Coughing	43 (36.4)	31 (35.2)	0.858
Body pain	24 (20.3)	14 (15.9)	0.419
Diarrhoea	17 (14.4)	9 (10.2)	0.373
Night sweats	30 (25.4)	15 (17)	0.151

P value obtained by Mann-Whitney U test

4.6.2 Food and snacks intake

Eighty percent of subjects in the FS + NC and 75.6% in the NC group reported consuming ≥ 3 meals in a day. Snacking was reported in only 26.7% of subjects in both groups (Table 10). Poor appetite accounted for 91.7% and 72.7% of subjects in the FS + NC and NC group respectively who reported taking 1-2 meals in a day.

Table 10: Frequency of meals and snacks intake

No. of meals and snacks	Meals intake		Snacks intake	
	FS + NC n=60	NC n=45	FS + NC n=60	NC n=45
	(%)	(%)	(%)	(%)
None	0	0	44 (73.3)	33 (73.3)
1-2 times	12 (20)	11 (24.4)	15 (25)	12 (26.7)
3-4 times	48 (80)	34 (75.6)	1 (1.7)	0
<i>P</i> value	0.586		0.469	

P value obtained by Chi square test

Poverty was not associated with the number of meals consumed in a day since 70.6% of subjects earning Kshs < 3,000 per month reported consuming 3-4 meals. Subjects who consumed 3-4 meals in a day had higher mean BMI ($17.8 \pm 1.6 \text{ kg/m}^2$) compared to those who consumed 1-2 meals ($16.6 \pm 1.6 \text{ kg/m}^2$).

4.6.3 Water treatment and consumption

Water treatment was reported by 46.7% and 51.1% of subjects in the FS + NC and NC respectively. Of these subjects, boiling was cited as the preferred method by 85.7% of subjects in FS + NC and 69.6% in the NC groups. For the subjects who did not boil water, 18.7% in the FS + NC and 31.8% in the NC group reported with diarrhoea. Few subjects in the FS + NC (11.7%) and NC (17.8%) groups reported drinking the recommended glasses of water per day.

4.6.4 Smoking and alcohol consumption

Smoking and alcohol consumption were uncommon among this cohort. Only 11.2% of subjects in the FS + NC and 6% in the NC group smoked cigarettes. When asked whether they drank alcohol, 12% and 4% of subject in the FS + NC and NC groups respectively answered in the affirmative.

4.6.5 Physical health

Only 15.2% of subjects in the FS + NC and 23.8% in the NC group reported performing physical exercises. Jogging, walking and weight lifting were mentioned as the exercises performed.

To assess perceived well-being and personal satisfaction, subjects were asked about their ability to perform daily activities. 35.5% and 36.7% of subjects in the FS + NC and NC groups respectively reported being unable to perform daily activities with relative ease in the previous month. 37.2% of subjects in the FS + NC group reported that they had poor physical health for between 15-30 days while 42.1% reported the same in the NC group. Only 23.6% and 21.1% of subjects in the FS + NC groups respectively reported having difficulty in performing daily activities due to body pain (Table 11). In the FS + NC group, 35.8% of subjects compared to 32.6% in the NC group required assistance in performing their daily activities. The difference however did not achieve statistical significance.

Table 11: Duration of poor physical health and pain that limited activities performance

	Poor physical health		Body pain	
	FS + NC n=110	NC n=90	FS + NC n=110	NC n=90
Days	(%)	(%)	(%)	(%)
0	42 (38.2)	35 (38.9)	64 (58.2)	57 (63.3)
1-14	27 (24.6)	17 (18.8)	20 (18.2)	14 (15.6)
15-30	41 (37.2)	38 (42.2)	26 (23.6)	19 (21.1)
<i>P</i> value	0.853		0.925	

P value obtained by Chi square test

Majority of subjects (29.1%) in the FS + NC group with marginal BMI (18.5-20 kg/m²) were not limited in performance of daily activities compared to 15.6% in the NC group ($P = 0.026$) as shown in Table 12.

Table 12: Distribution of undernutrition in performance of daily activities

BMI categories	Limited		Not limited	
	FS + NC n=110 (%)	NC n=90 (%)	FS + NC n=110 (%)	NC n=90 (%)
Undernourished	34 (30.9)	24 (26.7)	39 (35.5)	43 (47.8)
Marginal	5 (4.5)	9 (10)	32 (29.1)	14 (15.6)
<i>P</i> value	0.145		0.026	

P value obtained by Chi square test

4.6.6 Psychosocial health

i. Depressive symptoms

The results indicate that majority of subjects in both groups had depressive symptoms with varying duration (Table 13).

Table 13: Baseline distribution of the duration of depressive symptoms

Days	Negative feelings		Woke up fatigued		Inadequate sleep		Vitality	
	FS + NC n=60	NC n=45	FS + NC n=60	NC n=45	FS + NC n=60	NC n=45	FS + NC n=60	NC n=45
0	46(76.6%)	38(84.4%)	23(38.4%)	18(40%)	33(55%)	23(51.2%)	29(48.4%)	18(40%)
1 - 7	6(10%)	2(4.4%)	13(21.6%)	14(31.1%)	10(18.3%)	13(28.8%)	6(10%)	11(24.4%)
8 - 14	8(13.4%)	5(11.2%)	24(40%)	13(28.9%)	17(26.7%)	9(20%)	25(41.6%)	16(35.6%)
<i>P</i> value	0.512		0.404		0.280		0.335	

P value obtained by Chi square test

Increase in BMI was associated with increase in number of days that subjects felt energetic and full of life ($r = 0.420$; $P < 0.01$).

ii. Self esteem

Self-esteem reflects a person's overall self-appraisal of their own worth and encompasses both beliefs and emotions. In the cohort self-esteem was assessed by inquiring about the duration that subjects had any negative feelings of themselves by virtue of being HIV+. Though not statistically significant, 23.4% of subjects in the FS + NC group compared to 15.6% in the NC group reported having had negative feelings due to their HIV status during the previous 2 weeks.

iii. Stigma and discrimination

Overall, only 8.6% and 1.9% of subjects felt discriminated by close family members and friend respectively due to their HIV status. 90% in the FS + NC and 93.3% in NC group felt that their family members were respectful towards them. Similarly, 88.2% in the FS + NC and 87.8% in the NC group reported that they are always treated with respect by their persons other than family members. 86.4% in the FS + NC and 83.1% in the NC group reported that family members recognized and sympathized with their problems. These differences were however not statistically significant.

4.7 Health related quality of life after intervention

4.7.1 Morbidity

Equal proportion of subjects in both groups (58.6%) reported improved health status after intervention. The remaining 41.4% worsened or reported no change. The intervention also led to subjects reporting reduction in symptom burden as shown in Table 14.

Table 14: Change in prevalence of signs and symptoms

Sign/symptom	Groups	n	+ve change	-ve/No change	P value
			(%)	(%)	
Anorexia	FS + NC	60	27 (45)	33 (55)	0.833
	NC	36	17 (47.2)	19 (52.8)	
Nausea/vomiting	FS + NC	60	14 (23.3)	46 (76.7)	0.288
	NC	36	12 (33.3)	24 (66.7)	
Fatigue	FS + NC	60	17 (28.3)	43 (71.7)	0.607
	NC	36	12 (33.3)	24 (66.7)	

P values obtained by Chi square test

The intervention resulted in reduction of morbidity events by 1.5 ± 3.8 in the FS + NC and 1.6 ± 3.6 in the NC group.

4.7.2 Food and snacks intake

There was an increase in the proportion of subjects who reported increasing their meals intake per day in both groups. All the subjects in both groups reported taking between 3-4 meals in a day. Proportionately more subjects in the NC group (76.7%) had increased snacking compared to the FS + NC group (58.9%). Table 15 shows the food intake habits of the subjects.

Table 15: Proportion of change in food intake habits

Variable	n	Group	+ve change (%)	No change (%)	<i>P</i> value
Meals intake	42	FS + NC	38 (90.5)	4 (9.5)	0.668
	30	NC	28 (93.3)	2 (6.7)	
Snacking	42	FS + NC	26 (61.9.9)	16 (38.1)	0.103
	30	NC	24 (80)	6 (20)	

P values obtained by Chi square

4.7.3 Water treatment

The proportion of subjects who treated their drinking water increased in both groups as shown in Table 16.

Table 16: Change in the proportion of subjects who treated their drinking water

Groups	n	Baseline (%)	Month 3 (%)	Change (%)	<i>P</i> value
FS + NC	56	48.2	94.6	46.4	0.234
NC	30	56.7	96.3	39.6	

P values obtained by Chi square

4.7.4 Physical health

The increment in the proportion of subjects engaging in physical exercises was comparable between the FS + NC (32.1%) and NC (26.7%) group. Exercises of choice included walking, jogging/running and workouts.

The proportion of subjects reporting improved physical health after the intervention was compared between the groups (Table 17).

Table 17: Change in the proportion of subjects who reported limitation in performing daily activities due to poor physical health

Groups	n	+ve change	-ve/No change	<i>P</i> value
		(%)	(%)	
FS + NC	58	26 (44.8)	32 (55.2)	0.367
NC	41	22 (53.7)	19 (46.3)	

P values obtained by Chi square

Table 18 shows that equal proportion of subjects in both groups reported ability to perform daily activities with relative ease after the intervention.

Table 18: Change in the proportion of subjects limited in performing daily activities

Groups	n	+ve change	-ve/No change	<i>P</i> value
		(%)	(%)	
FS + NC	58	13 (22.4)	45 (77.6)	0.442
NC	41	12 (29.3)	29 (70.7)	

P values obtained by Chi square

4.7.5 Psychosocial health

Change in proportion of subjects with depressive symptoms

There was a general improvement in the proportion of subjects who had depressive symptoms after the intervention as shown in Table 19.

Table 19: Change in proportion of subjects with depressive symptoms

	Groups	n	+ ve change		P value
			(%)	no change (%)	
Inadequate sleep	FS + NC	42	17 (40.5)	25 (59.3)	1.000
	NC	30	16 (53.3)	14 (46.7)	
Negative feelings	FS + NC	42	9 (21.4)	33 (78.6)	0.106
	NC	30	4 (43.3)	26 (56.7)	
Woke up fatigued	FS + NC	42	21 (50)	21 (50)	0.719
	NC	30	13 (53.3)	17 (46.7)	
Vitality	FS + NC	42	17 (40.5)	25 (59.5)	0.968
	NC	30	12 (40)	18 (60)	

P values obtained by Chi square

The reduction in mean number of days that subjects had inadequate sleep was comparable between the groups (Table 20).

Table 20: Mean (SD) number of days that subjects had inadequate sleep

Groups	n	Baseline	Month 3	Mean difference	P value
FS + NC	58	6.7 (11.4)	2.7 (7.0)	4.0 (10.9)	0.375
NC	41	8.1 (11.2)	3.5 (8.1)	4.6 (11.2)	

P values obtained by student's t-test

CHAPTER FIVE

DISCUSSION

Maintenance of good nutritional status is considered a key intervention in stemming the undernutrition associated with HIV/AIDS. The results on body composition in this study indicate that BMI was comparable between men and women which conform to a study by Ludy *et al* (2005) in Thailand. The data provides an indication that CED using BMI categories can vary greatly in PLWHA. 70.8% of subjects were undernourished which is by far greater than the 41.3% ascertained by Ludy *et al* (2005) in a study examining the body composition of PLWHA in Khon Kaen, Thailand. Undernutrition in the subjects implies that they were at an increased risk of mortality (Satyanarayana *et al*, 1991) and ultimately shortened survival (Suttman *et al*, 1995). It can be concluded that inadequate dietary intake may have resulted in the low BMI values as subjects who consumed 3-4 meals in a day had higher mean BMI compared to those who consumed 1-2 meals ($P = 0.004$).

The increment in mean weight and BMI after the 1st month of follow up in the FS + NC group suggests a contribution by the food supplement to the build-up of fat stores. This was sustained in the subsequent second and third month of intervention. The results also indicate that subjects in the NC group gained less weight and BMI in the first 2 months of follow-up compared to the FS + NC group. However after the 3rd month, both groups had equal increments in mean weight and BMI. This implies that subjects may require several nutrition counseling sessions before positive results can be observed (Menezes, 2007) and points towards nutrition counseling having a positive effect on dietary intake in the NC

group (Burger *et al*, 1994). The lack of significant differences in anthropometric measures between the groups can be attributed to leakage of the food supplement.

Selective loss or addition of peripheral muscle and subcutaneous adipose tissue is reflected more in a change in MUAC than BMI (Ferro-luzzi and James, 1996). However, MUAC does not differentiate acute from chronic energy deficiency (Collins, 1996), hence cannot be used as a follow up indicator to assess malnutrition. Nevertheless, Ferro-luzzi and James, (1996) suggest that MUAC can be used as an additional criterion with BMI to identify the loss of peripheral muscle. Using MUAC as a measure of undernutrition, 64.4% of subjects in FS + NC and 56.7% in the NC group were undernourished. When applied together with BMI, 54.8% of subjects in FS + NC and 55.7% in NC were found to be undernourished. At baseline, BMI and MUAC were highly correlated in ($r = 0.646$; $P < 0.01$) which conforms to a study by Papathakis *et al* (2005) who also found a significant correlation ($P < 0.0001$). A regression analysis confirmed this relationship ($R^2 = 0.42$).

Weight gain has been suggested as a measure of the effect of food aid in interventions (Egge *et al*, 2005). Both groups recorded significant mean weight gain (3.3 kg) after 3 months of intervention. In the FS + NC group, this can be attributed to the effect of the food supplement in restoring weight as ascertained by Castleman (2008) who found a mean increment of 4.3 kg after 3.5 months of food intervention. The significant gain in the NC group reiterated the importance of nutrition counseling in the management of malnourished HIV-infected patients (Burger *et al*, 1994). The proportion of subjects who gained weight

was 81% in both groups. These results conform to a study by Niekerk *et al* (2000), who found that nutrition counseling assists PLWHA gain weight with 73% of subjects having stable or increasing weight after 4 months of follow up. Weight gain in the FS + NC after the intervention ($P < 0.01$) suggests a contribution by the food supplement to the rebuilding up of fat stores. In addition, the NC group also gained weight after the intervention ($P < 0.01$) suggesting the positive effect of nutrition counseling on dietary intake.

The functioning and well-being of patients with HIV is inextricably linked to the symptoms they experience (Lorenz *et al*, 2006). 55.6% of the subjects in the NC and 48.2% in the FS + NC group self reported having fair health status corresponding to HIV/AIDS clinical stage III. This was not statistically significant. After the intervention, equal proportions (58%) of subjects in both groups reported improved health status suggesting improved quality of life. Symptom burden was comparable between the groups. It is worth noting however that the mean symptom burden was 12 morbid events in both groups signifying that the subjects were experiencing multiple signs and symptoms associated with HIV. The reduction of morbidity events points towards the effectiveness of nutrition counseling in managing HIV related signs and symptoms.

Loss of appetite is a common problem in HIV infection (Kotler, 1998 and FAO, 2002). The overall prevalence of poor appetite (56.8%) suggests reduced food intake by subjects thus indicating that dietary requirements were not being met. Both groups recorded reduced incidence of poor appetite attributed to the effect of micronutrient fortified food supplement

(Deborah *et al*, 2003) and nutrition counseling in assisting subjects in management of poor appetite.

Overall, 51.5% of subjects reported feeling fatigue. This concurs with findings by Darko *et al* (1992), who established a range of between 48% and 57%. Studies have documented women reporting fatigue than men (Bensing *et al*, 1999), which can be attributed to the multi-tasking behaviour that is profound in women in their daily activities. However, the finding of this study did not establish gender difference in fatigue. The follow up data indicated that about one third of subjects in both groups reported reduced fatigue. The reason for this in the FS + NC group could be due to the supplementary effect of food supplement providing caloric energy to the subjects hence reducing fatigue (Nancy, 1991).

Diarrhoea in HIV infection can be caused by infection of the immune system within the gut increasing vulnerability to viral, bacterial or parasitic infections. In the cohort the prevalence was 12.6% which is half the 25% reported by Mazonson *et al*, (1992). Of the subject who experienced diarrhoea, water contamination may have been the cause as 65% did not treat their drinking water which may have contributed to the diarrhoea. Presence of body pain suggests inflammation due to tissue injury, infection or neoplasia and negatively impacts on the HRQOL of individuals (Larue *et al*, 1997). The prevalence of general body pain in the cohort was 18.4% which is lower than the 25% reported by Breitbart (1996). These findings correspond with medical evidence that indicates that AIDS patients, due to opportunistic infections, may experience levels of body pain and discomfort

Studies have suggested that physical activity and exercises contribute towards preventing fat accumulation in HIV/AIDS subjects (Florindo *et al*, 2007). The relative absence of performance of exercises by the study cohort may have been due to fatigue. The proportion of subjects who engaged in exercising after the intervention was comparable between the groups. However, a tendency of a higher increment in the FS + NC group underlines the positive effect of the food supplement in ensuring the subjects gained adequate strength to perform exercises. The increment in the NC group suggests the positive role played by nutrition education in changing subjects' attitude towards exercises and physical fitness.

Loss of strength as a result of prolonged illness and consequent poor dietary intake are a common occurrence in HIV. Majority (61%) of subjects in both groups reported inability to perform daily activities due to poor physical health. These results confirm the research conducted by Molassiotis *et al* (2001) who found that HIV/AIDS patients experience difficulty in their physical day-to-day role functioning. The observed reduction in physical activity incapacitation in the FS + NC group points towards the positive effect of food supplements in assisting PLWHA regain strength to undertake their daily activities (Personal communication). Undernutrition has been suggested to reduce work capacity and performance (Durnin 1994; Kennedy and Garcia 1994). However, the findings seem to suggest otherwise as the proportion of undernourished subjects who reported limitation in performance of activities was lower than those who reported no limitation.

Research has shown that sleeping for between 6-8 hours per night is optimal for health and a sustained reduction or increase in the duration may predispose one to ill-health and mortality (Ferrie *et al*, 2007). The proportion of subjects who got adequate sleep during the previous 30 days was comparable between the groups. The lack of adequate sleep can be attributed to psychological factors such as anxiety and depression (Lashley, 1999). All the subjects had one or more depression symptoms such as negative feelings, inadequate sleep, lack of vitality and waking up feeling fatigued. Other studies have reported depression of 37% (Fawzi *et al*, 2007) and 22% to 38% (Brown *et al*, 1992). The intervention resulted in an increase in the proportion of subjects who reported improvement in all the depression indicators. Increase in number of days that subjects felt energetic was most likely associated with increase in BMI ($r = 0.420$; $P < 0.01$). Sympathy towards PLWHA has been found to reduce stigma and discrimination (Norman *et al*, 2009). 93% of subjects in both groups felt that their family members were respectful towards them while 88% reported always being treated with respect by their persons other than family members.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

At baseline, the subjects had low nutritional status as evidenced by BMI below the WHO cut-off for underweight. In addition, the subjects reported poor physical activity level and self-reported health status coupled with multiple signs and symptoms indicating poor HRQOL. The intervention with a food supplement and nutrition counseling had a positive impact on nutritional status and so did nutrition counseling alone. This is corroborated by the equal weight and BMI increment in both groups after the intervention. This was evidenced by the significant increment in weight and BMI after 3 months of intervention. To obtain greater recovery rates in BMI, commencement of intervention with food supplements should be started when undernutrition is at its marginal stage (BMI 17–18.4 kg/m²) as indicated by the significant difference between the proportion of subjects who gained BMI in the FS + NC compared to the NC group. Interestingly, the intervention did not result in a significant improvement in HRQOL measures of self-reported health status, physical activity and psychosocial health in both groups. No significant differences in anthropometric and HRQOL measures between the FS + NC and NC groups were achieved and this can be attributed to leakage of the food supplement.

6.2 Recommendations

Rationale for food supplementation should be reviewed as nutrition counseling alone was seen to have similar impact in comparison with the food supplemented group.

Further controlled food supplementation studies with should with longer supplementation period are required. This can be achieved through conducting on-site observed feeding to prevent or reduce leakage.

Nutrition counseling should be enhanced in the comprehensive care of nutritionally vulnerable PLWHA. Basic nutrition counseling and education such as importance of food and what entails a balanced diet should be emphasized during counseling as they have a great impact on food intake patterns and ultimately nutritional status of PLWHA.

Provision of transport for the economically disadvantaged subjects' during clinic visits should be considered to reduce the rate of lost to follow up.

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APPENDICES

Appendix 1: Energy and nutrient content of the Insta Foundation food supplement

<i>Energy and nutrient content of Insta Foundation RDA for HIV+ men and women</i>				
Nutrient	Insta Foundation 300g/day	DRI ¹ Woman (HIV+ ²)	DRI Man (HIV+ ²)	Upper tolerable limits
Energy(kcal)	1360	2,900	3,340	-
Protein (g)	50	46	56	-
Calcium (mg)	258	1000	1000	2500
Phosphorus (mg)	1050	700	700	-
Magnesium (mg)	500	220	260	1080
Potassium (mg)	1700	4700	4700	6000
Selenium (µg)	22	55	55	400
Zinc (mg)	8	7	9	40
Copper (mg.)	2.9	1.2	1.2	10
Iron (mg)	16	20	9	45
Vitamin A (µg)	340	500	600	3000
Vitamin C (mg)	26	45	45	2000
Vitamin D (µg)	6	5	5	50
Vitamin E (mg)	32.5	5	5	1000
Niacin (mg)	13	14	16	200
Folic Acid (µg)	153	400	400	1000
Thiamine (mg)	1.3	1.1	1.2	600
Riboflavin (mg)	0.8	1.1	1.3	No recommendation
Vitamin B ₆ (mg)	1	1.3	1.3	100
Vitamin B ₁₂ (µg)	0.5	2.4	2.4	No recommendation

¹ DRI values for non-pregnant, non-lactating adults. Source: Food and Agricultural Organization of the United Nations and World Health Organization. *Human vitamin and mineral requirements*. Report of a joint FAO/WHO consultation. Bangkok, Thailand 1998.

² As per current WHO recommendations, protein and micronutrient requirements for HIV-positive adults are the same as for HIV-negative adults. Energy requirements increase by 10% for asymptomatic and 20-30% for symptomatic HIV-positive adults.

Appendix 2: WHO clinical staging of HIV/AIDS and case definition

Excellent health	Good health	Fair health	Poor health
Clinical stage 1	Clinical stage 2	Clinical stage 3	Clinical stage 4
<ul style="list-style-type: none"> • Asymptomatic • Persistent generalized lymphadenopathy 	<ul style="list-style-type: none"> • Moderate unexplained weight loss (<10% of presumed or measured body weight) • Recurrent respiratory infections (upper respiratory infections, sinusitis, bronchitis, otitis media, pharyngitis) • Herpes zoster • Minor mucocutaneous manifestations (angular cheilitis, recurrent oral ulcerations, seborrheic dermatitis, prurigo, papular pruritic eruptions, fungal fingernail infections) 	<ul style="list-style-type: none"> • Severe weight loss (>10% of presumed or measured body weight) • Unexplained chronic diarrhea for >1 month • Unexplained persistent fever for >1 month (intermittent or constant) • Oral candidiasis (thrush) • Oral hairy leukoplakia • Pulmonary TB within the last 2 years • Severe presumed bacterial infections (pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteremia) • Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis 	<ul style="list-style-type: none"> • HIV wasting syndrome, • <i>Pneumocystis jiroveci</i> (formerly <i>carinii</i>) pneumonia • Recurrent severe or radiologic bacterial pneumonia • Chronic herpes simplex infection (oral or genital, or anorectal site) for >1 month • Esophageal candidiasis • Extrapulmonary TB • Kaposi sarcoma • CNS toxoplasmosis • HIV encephalopathy

[3] Primary education, 5-8 yrs [7] Adult education

[4] Secondary Education, 9-12 yrs

3.4 What is/was your main occupation in the last month?

[1] Student [7] Casual worker/part-time

[2] Employed, unskilled labor [8] Farmer (large scale,
(building, plumbing, cleaners etc) subsistent , farming, gardening)

[3] Employed, skilled labor [9] Housewife

(technician or vocational skills such as

electrical, chemical, or mechanical

including car repair, carpentry etc)

[4] Agricultural/forestry worker [10] Unemployed

[5] Business (self employed) [11] Attendant in hotels, guest
house, bars, or clubs

[6] Professional (Teacher, doctor, [12] Other (specify) _____
nurse, manager, accountant etc) _____

4. Socio-economic information

4.1 In the last month, what was the income of your household (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 [8] None

4.2 Excluding yourself, how many people live with you in your house?

Total # _____ of people

4.3 Excluding yourself, how many people who live with you by to their sex and age:

[1] Adults > 18 years	Females:	<table border="1"><tr><td></td><td></td></tr></table>			Males:	<table border="1"><tr><td></td><td></td></tr></table>		
[2] Children 5 – 18 years	Females:	<table border="1"><tr><td></td><td></td></tr></table>			Males:	<table border="1"><tr><td></td><td></td></tr></table>		
[3] Children <5 years	Females:	<table border="1"><tr><td></td><td></td></tr></table>			Males:	<table border="1"><tr><td></td><td></td></tr></table>		

5. Behavioral and health habits

5.1 Do you smoke cigarette?

[1] Never (no history of smoking) [3] Smoked in the past (past smoker)

[2] Currently smoking [88] Don't know

5.2 Do you drink alcohol?

[1] Never [3] Drank alcohol in the past

[2] Currently drinking alcohol [88] Don't know

5.3 Do you perform exercises at least 2 times a week?

[1] No [2] Yes

Appendix 4: Quality of life assessment

To be completed at Baseline and Month 3

Serial number

1. Basic information

1.1 Date of interview (dd/mm/yy)

1.2 Food group 1) Food 2) Nutrition Counseling

1.3 Name of Study Participant _____

2. Healthy days

Instructions to the study participant:

I am now going to ask you questions about your health and well-being to assess your healthy days, any activity limitations and symptoms that you might have experienced during the past 30 days.

2.1 Overall, how satisfied are you with your life these days? (read responses #1-4 only):

[1] Very satisfied [3] Unsatisfied [88] Don't Know
[2] Satisfied [4] Very unsatisfied [99] No response

2.2 Would you say that in general your health is (read responses #1-5 only):

[1] Excellent [4] Fair [88] Don't Know
[2] Very good [5] Poor [99] No response
[3] Good

2.3 Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?

_____ # days [00] None

[88] Don't know/Not sure [99] No response

2.4 Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?

_____ # days

[00] None

--	--

[88] Don't know/Not sure

[99] No response

2.4 During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?

_____ # days

[00] None

--	--

[88] Don't know/Not sure

[99] No response

3. Activity limitations

The next set of questions will inquire about your physical, or emotional problems, or limitations you may have in your daily life.

3.1 Are you LIMITED in any way in any activities because of any impairment or health problem?

[1] No

[88] Don't know/Not sure

--

[2] Yes

[99] No response

4. Healthy days symptoms

4.1 During the past 30 days, for about how many days did PAIN make it hard for you to do your usual activities, such as self-care, work, or recreation?

_____ # days

[00] None

--	--

[88] Don't know/Not sure [99] No response _____

4.2 During the past 30 days, for about how many days have you felt sad, blue, or depressed?

_____ # days

[00] None

--	--

[88] Don't know/Not sure

[99] No response

4.3 During the past 30 days, for about how many days have you felt worried, tense, or anxious?

_____ # days

[00] None

--	--

[88] Don't know/Not sure

[99] No response

4.4 During the past 30 days, for about how many days have you felt you did NOT get enough sleep?

_____ # days

[00] None

--	--

[88] Don't know/Not sure

[99] No response

4.5 During the past 30 days, for about how many days have you felt very healthy and full of energy?

_____ # days

[00] None

--	--

[88] Don't know/Not sure

[99] No response

5. Interactions

5.1 Which of the following statements best characterizes how **your spouse and other family members** behave toward you?

[1] They always treat you with respect.

[88] Don't Know

--

[2] They usually treat you with respect. [99] No response

[3] They often do not treat you with respect.

[4] They rarely or never treat you with respect.

5.2 Which of the following statements best characterizes how your **spouse and other family members** view your problems and needs?

[1] They recognize and sympathize with your problems and needs.

[2] They recognize your problems and needs but do not sympathize with them.

[3] They do not recognize or sympathize with your problems and needs.

[4] They deliberately ignore or worsen your problems and needs.

[88] Don't know

[4] No response

5.3 To what extent do **your spouse and other family members** recognize and value you as a human being?

[1] Fully. [88] Don't Know

[2] Somewhat. [99] No response

[3] Not very much.

[4] Not at all.

5.4 Which of the following statements best characterizes how **your employer, neighbors, and other non-family members** behave toward you?

[1] They always treat you with respect.

[2] They usually treat you with respect.

[3] They often do not treat you with respect.

[4] They rarely or never treat you with respect.

[88] Don't know

[99] No response

5.5 Which of the following statements best characterizes how **your employer, neighbors, and other non-family members** view your problems and needs?

[1] They recognize and sympathize with your problems and needs.

[2] They recognize your problems and needs but do not sympathize with them

[3] They do not recognize or sympathize with your problems and needs.

[4] They deliberately ignore or worsen your problems and needs.

[88] Don't know

[99] No response

5.3 To what extent do **your employer, neighbors, and other non-family members** recognize and value you as a human being?

[1] Fully.

[2] Somewhat.

[3] Not very much.

[4] Not at all.

[88] Don't know

[99] No response

Appendix 5: Morbidity assessment

To be completed at Baseline and Month 3

Serial number

1. Basic information

1.1 Date of interview (dd/mm/yy)

1.2 Food group 1) Food 2) Nutrition Counseling

1.3 Name of Study Participant

2. Clinical signs and symptoms

2.1 Have you experienced any of the following symptoms or diseases:	Today? [1] No [2] Yes [88] DK [99] NA	In the past one month? [00] No [# of Days] Yes [66] Yes, but DK # of days [88] DK [99] NA	
Headaches			
Dizziness			
General body pain			
Sore throat			
Coughing			
Fever			
Fatigue			

Mouth sores/ulcers			
Diarrhoea			
Change in taste			
Loss of appetite			
Nausea/Vomiting			
Constipation			
Itchy skin rash			
Non itchy skin rash			
Enlarged lymph Nodes			
Loss of sleep			
Shortness of breath			
Brittle hair			
Chest pains			

Appendix 6: Additional questions

Serial number

A: Food and water consumption

1.1 On average, how many main meals do you usually eat in a day?

- 1) 1
- 2) 2
- 3) 3
- 4) 4_≥

1.2 If fewer than the recommended 3 meals (Q23), what is the reason(s)?

- 1. Poor appetite
- 2. Lack of food
- 3. Too much work
- 4. Too sick to eat
- 5. Other (specify) _____
- 99. N/A

1.3 On average, how many times do you eat snacks in a day?

- 1. 1
- 2. 2
- 3. 3
- 4. 4_≥

1.4 On average, how many glasses of water do you drink in a day?

_____ Glasses

00 None

88. Don't know/not sure

a. Do you treat your water before drinking?

2. Yes

3. No

a. If yes, how?

2. Boil

3. Put chemicals

4. Other (Specify) _____

99. N/A

a. How often do you treat your water before drinking?

2. Always

3. Sometimes

4. Never

B: Physical health

2.1 During the **past 2 weeks**, for how many days were you **unable** to perform your daily activities because of illness?

_____ Days

00. None

88. Don't know/not sure

2.2 During the **past 2 week**, for how many days did **body pain** interfere with your normal activities?

_____ Days

00. None

88. Don't know/not sure

C: Psychosocial functioning

3.1 How many hours of sleep do you have at night?

_____ Hours

88. Don't know/not sure From To

3.2 How many hours did you sleep yesterday?

_____ Hours

88. Don't know/not sure From To

3.3 During the **past 2 weeks**, how many days did you **not** get enough sleep?

_____ Days

00 None

88. Don't know/not sure

3.4 During the **past 2 weeks**, for how many days did you wake up feeling tired or fatigued?

_____ Days

00 None

88. Don't know/not sure

3.5 During the **past 2 weeks**, for how many days did you have negative feelings such as blue mood, despair, anxiety because of being HIV positive?

_____ Days

00 None

88. Don't know/not sure

3.6 Do your family members/relatives discriminate/isolate/ridicule you for being HIV positive?

1. Yes

2. No

3. They don't know my status

a. Do your workmates discriminate/isolate/ridicule you for being HIV positive?

1. Yes

2. No

3. They don't know my status

99. N/A

a. Do your friends/neighbours discriminate/isolate/ridicule you for being HIV positive?

1. Yes

2. No

3. They don't know my status

a. Do you feel guilty about being HIV positive?

1. Yes

2. No

b. Do you feel anger/towards the person who may have infected you with HIV?

1. Yes

2. No

Appendix 7: Consent form

Effect of food supplementation on health-related quality of life among HIV-infected adults attending Naivasha district hospital

Introduction

My name is Fred Mike Alumasa an MPH student at Jomo Kenyatta University of Agriculture and Technology undertaking research for my Thesis. The study aims to establish whether food supplementation improves the health-related quality of life of people with HIV/AIDS. I would like to ask you questions regarding your health and well-being.

Participation in the study

Participation is entirely voluntary. You will be required to undergo standard medical examination at the clinic to confirm your eligibility for the study. Upon enrolment into the study, you will be *randomly* allocated to either of 2 groups to receive either nutrition counseling or nutrition counseling and supplementary food for 3 months. You will then be asked detailed questions regarding yourself and your health, and anthropometric measurements of weight, height, MUAC and BIA taken. However, if you choose not to participate in the study, it will not affect your access to clinical care at this facility. You will be able to receive the same medical treatment and nutrition counseling as other clients at the facility. All information you provide will remain strictly confidential. Only the study team will have access to this information and it will not be relayed to any other persons unless you give your permission.

Benefits for participating clients

- ❖ Anthropometric assessments at baseline and after 3 months
- ❖ Nutrition counseling on what you need to eat for your condition

Participation Information

You are being requested to participate in this research study.

1. You may withdraw from participating in the study at any time without giving the reason and without jeopardizing your right to medical and nutritional care, or your participation in other feeding programs.
2. Please feel free to ask any questions on anything that is not clear to you, after you have read and had the consent form explained to you.

Confirmation of consent

I the undersigned have understood the above information concerning this study which has been fully explained to me and I understand what will be required of me if I take part in the study. I had the opportunity to ask questions which were answered to my satisfaction. I understand that at any time that I may wish to withdraw from this study I can do so without giving any reason and without affecting my access to normal health care and management.

I agree to take part in this study.

Name _____

Signed _____ Date _____

Appendix 8: Baseline distribution of chronic energy deficiency grades

		CED Categories					
		n	CED I	CED II	CED III	Marginal	Normal
BMI (kg/m ²)	FS + NC	125	47 (37.6%)	14 (11.2%)	23 (18.4%)	41 (32.8%)	-
	NC	101	40 (39.6%)	19 (18.8%)	16 (15.8%)	26 (25.7%)	-
MUAC (cm)	FS + NC	118	2 (1.7%)	4 (3.4%)	8 (6.8%)	70 (59.3%)	34 (28.8%)
	NC	88	2 (2.3%)	1 (1.1%)	2 (2.3%)	54 (61.4%)	29 (33%)