EFFECT OF FOOD SUPPLEMENTATION ON NUTRITIONAL AND MORBIDITY STATUS OF HIV INFECTED ADULTS RECEIVING ANTIRETROVIRAL THERAPY

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BSc, Hotel and Institutional Management

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A DISSERTATION PRESENTED TO THE DEPARTMENT OF FOOD SCIENCE, NUTRITION AND TECHNOLOGY UNIVERSITY OF NAIROBI, IN PARTIAL FULLFILMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN APPLIED HUMAN NUTRITION

Declaration

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

Signature: _____ Date: 18/08/2009

This dissertation has been submitted for examination with my approval as University supervisor.

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Dedication

This work is dedicated to my loving mother GRACE PENINAH OBUYA for her constant prayers, encouragement, support and believing in me; for being a wonderful mother. May the almighty God bless her in abundance. Glory unto God!

Acknowledgements

This study would not have been possible without the assistance of my supervisor Dr. A. M. Mwangi and the input of Dr. A. M. Omwega. I am thankful for their advice, helpful materials and suggestions starting from proposal development to the fieldwork and during the preparation of this dissertation.

I would like to thank Food and Nutrition Technical Assistance project in collaboration with Kenya Medical Research Institute for sponsoring this research. I am grateful to the respondents who took part in the study and the research team Mrs. Salma Ali, Mr. Eustace Gitonga, Dr. Ken Meme and Mr. Richard Mutisya for their continuous assistance during data collection. This study was funded by Food and Nutrition Technical Assistance project through collaboration with Kenya Medical Research Institute and Applied Nutrition Programme (ANP) of University of Nairobi.

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Lastly, I would like to thank my heavenly Father for giving me the ability and strength to undertake this study; for being faithful to me.

May the Almighty God bless you all!

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List of Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral-therapy
ARV	Antiretroviral Drug
BMI	Body Mass Index
CBS	Central Bureau of Statistics
CCC	Comprehensive Care Clinic
CDC	Center for Disease Control and Prevention
FANTA	Food and Nutrition Technical Assistance
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
IDDS	Individual Dietary Diversity Score
KDHS	Kenya Demographic Health Survey
KEMRI	Kenya Medical Research Institute
NDP	National Development Plan
NGO	Non-governmental Organization
PLWHA	People Living with HIV/AIDS
RDA	Recommended Daily Allowance
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

Operational Definitions

Aids_ a condition resulting from a group of illnesses in form of opportunistic infections caused by the human immunodeficiency virus, which weakens the immune system.

Adherence_ compliance in taking medications correctly and on time; encompasses the patient's active participation in his or her own healthcare, seeking medical advice, keeping appointments, following recommendations concerning lifestyle as well as following medical regimens.

Antibody_ a protein that is manufactured by lymphocytes to neutralize an antigen or foreign protein.

Body Mass Index_ a measure based on weight in kilograms divided by the square of height in meters that indicates nutritional status in adults.

CD4_ type of white blood cells which organize the immune system's response to some micro organisms including bacterial, viral, fungal and protozoa infections.

Dietary Diversity_ the number of food groups consumed in the reference period, in this study 14 food groups (for Individual Dietary Diversity Score) was used.

Fortification_ addition of one or more nutrients to food.

Highly active antiretroviral therapy_ a combination of three or more antiretroviral drugs used in the treatment of HIV infected people to progressively suppress viral replication and progress of disease.

HIV infected_ refers to people who are infected with HIV whether or not they are aware of it.

HIV positive_ refers to people who have taken an HIV test and who know that they tested positive.

Malnutrition_ a condition caused by deficiencies, excesses or imbalance in energy, protein and, or other nutrients (in this study it refers to under nutrition, inadequate intake of food energy and lack of nutrients).

Mid Upper Arm Circumference_ is a measure of muscle and subcutaneous adipose tissue done on the mid-upper arm; used to assess total body mass and in some circumstances, protein-energy malnutrition.

Nutritional anthropometry_ is the measurement of the variations of the physical dimensions or gross composition of the human body.

Nutritional status_ a measurement of the extent to which an individual's physiological needs for nutrients are being met; in this case, anthropometric measurements. .

Opportunistic infections_ denotes an infection by a micro-organism which does not ordinarily cause disease but becomes infectious under certain conditions such as when the immune system is impaired.

Recommended Daily Allowance_ the average daily dietary nutrient intake level, sufficient to meet the nutrient requirements of nearly all (97 to 98%) healthy individuals in a particular life stage and gender group.

Supplementation_ provision of special dose of nutrient preparation which may be in form of a tablet, capsule, oil solutions or modified food, for either treating an identified deficiency or prevention of the occurrence of such deficiency in an individual or a community.

Abstract

Clinical studies to evaluate the role of supplementary foods or nutrition therapy in reversing malnutrition and its impact on health and survival have not been done in Human immunodeficiency virus-infected individuals living in resource poor settings. The main objective of this study was to assess the effect of food supplementation on nutritional status and morbidity experience of malnourished human immunodeficiency virus infected adults receiving antiretroviral therapy.

The study was conducted from July 2006 to April 2007, as part of a larger study located in three sites within Kenya, in Maragua District Hospital, Mathare North Health Centre and Riruta City Council Hospital. A total of 147 clients receiving antiretroviral therapy and nutritional counseling were recruited. Of these clients, 83 as study group and were put on 300g food supplement per day for a period of three months, while 64 served as the control group. The food supplement was a blend of maize, soya, sugar, palm oil, and micronutrients pre-mix, composed of 45% of the total energy required by an adult in the symptomatic stage according to World Health Organization recommendation.

Data were also collected on demographic and socio-economic characteristics, anthropometry, morbidity experience, dietary patterns and adherence to supplement intake regime. Data on anthropometry and morbidity were collected initially and at monthly intervals during the feeding trials, while demographic and socio-economic data were collected at baseline only; and dietary patterns both at baseline and after 3 months. Data were analysed using Statistical Package for Social Sciences version 12.0, and excel. Difference in the outcome variables were tested at $p<0.05$.

A greater proportion (60 %) of clients in the study sample were females. Most clients were in monogamous marriages and had some formal education. The mean age was 35.1±2.9 while the mean household size was 3.7±7.3. There was a significant difference (p=0.000) in the main source of income between the two groups. The clients on food supplement relied on casual labor and remittances while the control group relied on farming as their main source of income.

At baseline there was no significant difference in weight and body mass index between groups while the mid upper arm circumference among the food supplement group was significantly lower. After three months of follow-up, the mean body mass index of the food supplement group was significantly higher (p=0.019) than that of the control group. Although mean mid upper arm circumference and body mass index increased in both groups, the increments were significantly higher among the food supplement group than the control group. After three months of nutrition counseling, both groups showed a similar increase in consumption of diverse foods. Morbidity experience significantly reduced in both groups by the third month of follow up.

This study concludes that combined food supplementation and nutritional counseling significantly improves the anthropometric status, morbidity experience and dietary intake of HIV infected adults on antiretroviral therapy. While nutrition counseling alone also impacts positively to nutritional status, morbidity experience and dietary intake the effect is even better when coupled with food supplement in resource poor communities with poor purchasing power. It is recommended that nutrition education among HIV positive people in resource poor communities be strengthened, coupled with activities that improve and strengthen their resource capacities and purchasing power to improve food security.

CHAPTER 1

INTRODUCTION

1.1 Background

Two decades into the pandemic, the incidences of human immunodeficiency virus (HIV) infection are still unacceptably high; making this a serious health challenge for the new millennium. Approximately 40 million people were living with HIV worldwide by 2006 (UNAIDS/WHO, 2006); in 2007, the estimated number was 33.2 million (UNAIDS/WHO, 2007). Sub-Saharan Africa, where malnutrition and food insecurity are endemic remains the region most affected. Most victims are adults in the prime of productivity and almost one-third are women.

At both national and family level, the HIV epidemic has weakened societies and economic status in Africa, making it difficult to ensure food security, education and other basic services (Piwoz and Preble, 2000). In Kenya, the national HIV prevalence rate is currently estimated at 5.1 % (NASCOP and NACC, 2007).

The recent improved coverage in treatment of opportunistic infections and use of antiretroviral therapy (ART) are expected to be accompanied by declined prevalence of wasting among HIV clients. Wasting is caused by numerous associated complications that include increased metabolic demand for nutrients without accompanied increase in dietary intake, chronic diarrhea and other opportunistic infections, malignancy and/or, in Africa, by starvation secondary to poverty (Abrams, 2000); anorexia, malabsorption, and systemic infections (Kotler, 1994) which in turn affects the nutritional and immunological status of the HIV+ individuals.

In patients with HIV infection, poor nutritional status reduces survival (Suttmann *et al.*, 1996; Guenter *et al.*, 1993; Kotler *et al.*, 1989), accelerates progression to AIDS, (Wheeler *et al.*, 1998), reduces the capacity to prevent opportunistic infections, maintain daily functioning and strength (Grinspoon *et al.*, 1999), and may diminish response to therapies including ART. Therefore, nutrition interventions have been suggested to increase energy intake and provide recommended protein and micronutrient intakes to HIV infected persons. This may help in improving their nutritional status, management of the disease, especially in prolonging life and

delaying the progression of full-blown AIDS. The present study was part of a continuing wider project by Kenya Medical Research Institute (KEMRI) and Academy for Educational Development/Food and Nutrition Technical Assistance (AED/FANTA) project, aimed at elucidating the importance of adequate nutrition on the nutritional status of malnourished HIV positive persons on ART.

1.2 Problem Statement

In Africa, wasting in HIV-infected adults is a manifestation of severe nutritional deficiency, worsened by poverty (Piwoz and Preble, 2000). HIV infected individuals require additional nutrients as their bodies are often deficient in, or require extra energy, protein, vitamins and other nutrients. Lack of provision of energy and nutrients to the body results in poor nutritional status.

Although antiretrovirals (ARVs) have been found to contribute to maintenance of health and avoidance of weight loss (Silva *et al.*, 1998), malnutrition and wasting are still common among HIV-infected patients on ARV treatment even in developed countries (Wanke *et al.*, 2000). This may be due, in part, to the effect that chronic malnutrition in resource poor settings may have on intake, absorption and utilization of both food and drugs.

Provision of energy dense foods has been suggested by some investigators to be effective in increasing weight gain in HIV infected individuals who are wasted or losing weight (Kotler, 2000). It remains unclear (Piwoz and Preble, 2000) how nutrition therapy or supplementation might positively affect malnourished HIV positive individuals on ART and the present study addresses this gap.

1.3 Justification of the Study

Improved nutrition can help attain the Millennium Development Goals (MDGs) of "Combating HIV/AIDS" (SCN, 2004), and it is also an indicator of poverty and hunger. Good nutritional status slows the onset of AIDS in HIV-positive individuals. Clinical studies to evaluate the role of food supplements on reversing wasting and its impact on health and survival have not been done in HIV positive individuals on ART and living in resource poor settings. In such settings, both nutrition and other medical therapies would be needed to achieve medical management of

AIDS patients (Grinspoon and Mulligan, 2003); hence, a high calorie diet is required for patients with volume intolerances, and barriers to adequate intake in order to restore and maintain nutritional status. The effects of ARVs are less known in people with poor nutritional diets than in people with good nutritional diets.

In addition, as Kenya scales up ART services, there is a critical need for information about the impact of appropriate food supplements on the effectiveness of ART, the health and nutritional status of clients, and on the progression of the disease. Therefore, this study was conducted in three sites in Kenya, to contribute towards the much needed data to establish the effect of food supplementation on nutritional status and morbidity experience of malnourished HIV positive adults receiving ART in resource poor settings.

1.4 Aim

The aim of the study was to improve the health and nutritional status of HIV positive adults.

1.5 Purpose

The purpose of the study was to establish the importance of adequate nutrition on well being of HIV positive adults.

1.6 General Objective

The main objective of the study was to assess the effect of food supplementation on nutritional status and morbidity experience of malnourished symptomatic HIV positive adults receiving ART.

1.6.1 *Specific objectives*

The sub-objectives were;-

1. To determine demographic and socio-economic characteristics of malnourished HIV infected adults on ART.
2. To assess the nutritional status (body weight, MUAC and BMI) of the study group at baseline and after 3 months of daily supplementation.
3. To assess the dietary patterns of the study clients.

4. To determine the morbidity of the clients at baseline and after 3months of daily supplementation.

1. 7 Hypothesis

Food supplementation improves the nutritional status and morbidity experience of malnourished HIV infected adults receiving ART.

1. 8 Research Question

The main research question in the study was "Does food supplementation improve the nutritional status and morbidity experience of malnourished HIV positive adults receiving ART after 3 months of daily supplementation?"

1.9 Limitations of the Study

Limitations of the study were; short follow-up period due to time constraints and some clients decided to drop out and a few refused to take the food supplement. Controlling adherence to the supplement was difficult and some clients either shared the supplement or did not take the daily proportion as required (took < 300g/day).

1. 10 Assumption

The study assumed that the sample was drawn from a normally distributed population and was representative of the areas' population in view of their demographic and socio-economic characteristics.

CHAPTER 2

LITERATURE REVIEW

2.1 HIV and Disease Progression

Acquired immunodeficiency syndrome (AIDS) is a condition caused by a retrovirus known as human immunodeficiency virus (HIV) which attacks and impairs the body's natural system against disease and infection. The virus can live in a person for several years slowly impairing the defense system, thereby allowing other viruses, bacteria and parasites to further weaken the body and cause various repeated illnesses, such as pneumonia, tuberculosis and oral thrush. The individual goes through four different clinical stages (Table 1). HIV progressively damages the immune system, which can make a person susceptible to a range of opportunistic infections and lead to conditions such as weight loss, fever and diarrhea.

A person has AIDS when he/she starts having opportunistic infections. The amount of time it takes from HIV infection to become full-blown AIDS depends on the general health and nutritional status. Therefore, good nutrition and health is essential in delaying progression to AIDS-related diseases.

Table 1: WHO Clinical Stages for HIV Infected Adults and Adolescents

STAGE	CLINICAL DESCRIPTION	SYMPTOMS	PERFORMANCE SCALE
I	Asymptomatic	Persistent generalized swelling of the lymph nodes	Normal activity
II	Symptomatic	Weight loss < 10% body weight; Minor symptoms and infection	Normal activity
III	Symptomatic	Weight loss >10% body weight, Chronic diarrhea >1month, oral thrush, fever >1month, pulmonary tuberculosis, pneumonia	Bedridden <50% of the day for the past month
IV (AIDS)	Symptomatic	HIV wasting syndrome, Severe opportunistic infections	Bedridden >50% of the day during the last month

Source: WHO, 2003b

2.2 Nutrition and HIV

Nutrition, as defined by Raiten, (1991), is the processes involved in the taking in and utilization of food substances by which growth, repair, and maintenance of the body or in any of its parts are accomplished. The processes of nutrition include ingestion, digestion, absorption and metabolism (including transport to and from target tissues and functional utilization of dependent systems) thus, an essential part of any HIV care package. Although improved nutrition is not enough in itself to permanently keep people healthy, it may help prolong the period of time between HIV infection and the onset of opportunistic infections (take advantage of the opportunity offered by a weakened immune system).

HIV-related conditions can lower food intake by reducing appetite and interfering with the body's ability to absorb food. Research suggests that good nutrition strengthens the immune system, increases resistance to infection and leads to better management of HIV-related complications (Figure 1) .

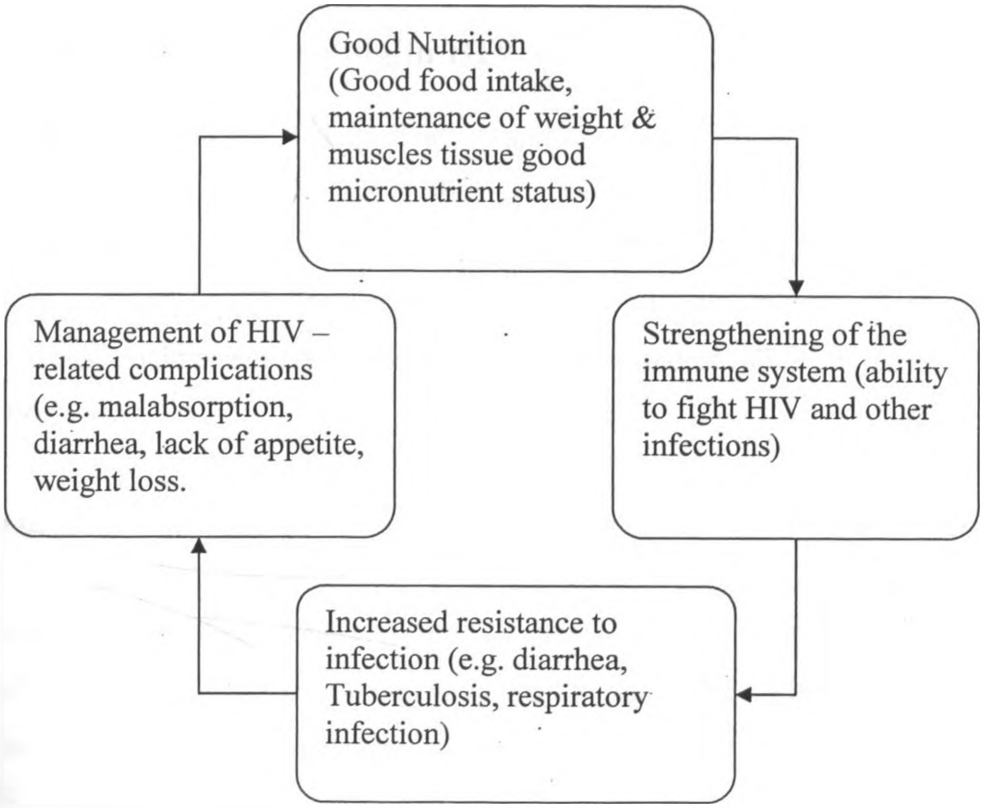

Figure 1: The cycle of good nutrition and resistance to infection
Source: WHO/FAO, 2002

2.3 Malnutrition in HIV Infected Adults

HIV has been superimposed on condition of severe malnutrition in which HIV comprises a patient's nutritional status and malnutrition worsens its' effect. Research suggests that malnutrition increases the risk of progression of HIV infection in adults. In turn, HIV infection makes malnutrition worse through its attacks on the immune system and its impact on nutrient intake, absorption and the body's use of food.

It is established that HIV infection can lead to under nutrition, including micronutrient deficiencies and lean body mass depletion through decreased food intake, malabsorption, increased utilization and excretion of nutrients (Piwoz and Preble, 2000; Keusch and Farthing, 1990) thus resulting in poor nutritional status. In a 12-week study of patients with AIDS wasting, a supplement containing glutamine was shown to increase lean body mass by 1.7kg as compared with only 0.4kg in the placebo-treated group (Shabert *et al.*, 1999).Therefore it is possible that good nutrition can reverse the condition of AIDS wasting.

2.4 Weight Loss and Wasting in HIV

In 1987, the U.S. Centers for Disease Control and Prevention (CDC) recognized wasting as an AIDS-defining condition. Weight loss is often the event that begins a vicious circle of increased fatigue and decreased physical activity, including the inability to prepare and consume food and reduced work productivity. The potential causes include; decreased dietary intake, opportunistic infections (which could affect the processes of nutrition) and/or metabolic changes secondary to HIV infection itself.

Reduction in food intake may be due to painful sores in the mouth; fatigue, depression, changes in mental state and other psychological factors may also play a role by affecting a person's appetite and interest in food (FANTA, 2004; Piwoz and Preble, 2000). Economic factors also affect food availability and the nutritional quality of food. Side effects (WHO, 2003b) from medications can also result in lower dietary intakes that can cause weight loss associated with HIV/AIDS.

Malabsorption accompanies the frequent bouts of diarrhea that affect people with HIV as a result of various infections (Piwoz and Preble, 2000). It is also believed (WHO, 2003a; Macallan, 1999) that HIV infection itself may cause nutrient malabsorption; increased energy and protein need as well as inefficient use and loss of nutrients. In addition, it may also result in loss of appetite leading to weight loss.

Changes in metabolism occur from severe reductions in food intake as well as from the immune system's response to the infection. When food is restricted, the body responds by altering insulin and glucagon production, which regulate the flow of sugar and other nutrients in the intestine, blood, liver and other body tissues. Over time, the body uses up its carbohydrate stores from muscle and liver tissue and it begins to break down body protein to produce glucose. This process causes protein loss and muscle wasting (Piwoz and Preble, 2000).

2.5 Nutritional Requirements for HIV Infected Adults

The recommendations for nutritional requirements of HIV infected adults are based on the report of WHO, 2003a. Individual requirements vary more widely in persons with HIV infection, owing to the variable presence of increased rates of resting energy expenditure or reduced activity levels.

2.5.1 *Macronutrients*

Energy requirements are increased by 10% for the maintenance of body weight and physical activity in asymptomatic HIV-infected adults (WHO, 2003a). Increased energy intake of about 20 percent to 30 percent is recommended for adults during periods of symptomatic disease or opportunistic infection to maintain body weight; as low energy intake combined with increased energy demands due to HIV-infection and related infections have been found to be the major driving force behind HIV related weight loss and wasting.

The recommended level of protein intake in healthy adults is 0.8 g/kg, and although no specific protein requirements have been determined for HIV-infected patients, it is frequently recommended that they consume 1.5 g/kg per day; though with no current sufficient data to support this. High supplements alone do not prevent wasting or an increase in muscle mass. According to WHO, 2003a protein requirements remain the same as for healthy individuals, that

is 12% to15% of total energy intake. However, since energy requirements are higher, protein intake should increase proportionately with efforts to increase energy intake. In addition, there are other factors that increase protein needs which are: illness, surgery, infection, trauma, and pressure ulcers. It is, therefore, important to consider pre-existing or concurrent protein deficiencies.

There is no evidence that fat requirements are different because of HIV infection. The recommended intake for fat in a healthy adult is 30% to 35% of the total energy needs. However, special advice might be required for individuals undergoing antiretroviral therapy or experiencing diarrhea.

2.5.2 *Micronutrients*

Micronutrient deficiencies such as vitamin A, B-complex, C and E; and selenium, iron, zinc, beta-carotene, folate and magnesium are prevalent in many HIV-infected populations (Kupka and Fawzi, 2002; Semba and Tang, 1999; Friis and Michaelson, 1998), and numerous studies have reported that these deficiencies impair immune responses, weaken epithelial integrity, and are associated with accelerated HIV disease progression. Deficiencies of anti oxidant vitamins and minerals contribute to oxidative stress, a condition that may accelerate immune cell death and increase the rate of HIV replication (Allard *et al.*, 1998; Schwarz, 1996).

Additional micronutrient intakes above or below the recommended dietary allowance (RDA) levels are not recommended for HIV individuals. However, caution is to be exercised as excessive amounts of some micronutrients, such as vitamin A, E, zinc and iron have been shown to impair or speed up disease progression rather than improve the immune system (Marston and DeCock, 2004; Shevitz and Knox, 2001; Piwoz and Preble, 2000; McKinley *et al.*, 1994).

2.6 Macronutrients – Micronutrients Interaction

Macronutrients (carbohydrates, proteins and fats) are nutrients that the body uses in relatively large amounts. This is as opposed to micronutrients, which the body requires in smaller amounts, such as vitamins and minerals. Macronutrients provide calories to the body as well as performing other functions. But, without sufficient quantities of micronutrients available energy of the

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macronutrients cannot be released as vitamins and minerals energize and regulate their metabolism (Berneis *et al.*, 2000).

Neither vitamins nor minerals can be assimilated alone or function without the aid of one another. In addition, certain combinations of Vitamins and minerals are antagonistic; they work against each other, while others are synergistic; that is, they enhance the activity of one another. In turn, macronutrients sometimes work antagonistically and synergistically with the micronutrients as in the case of calcium/lipids and the fat soluble vitamins/lipids. In particular, vitamin A requires fats as well as minerals to be properly absorbed. It protects vitamin C from oxidation which allows it to work better. Vitamin C may also be required to achieve optimum conversion of vitamin D which is essential for the body to properly utilize calcium and phosphorus; in addition to assimilating vitamin A. Besides, vitamin K works synergistically with other B vitamins as well as A, E and C; thus, too little vitamin A interferes with the ability of the digestive system to synthesize vitamin K. A properly functioning thyroid gland helps vitamin B_{12} absorption; folate also works closely with vitamin B_{12} (Berger *et al.*, 1993; Dowling *et al.*, 1990).

As with vitamins, some minerals are necessary in specific quantities and in certain combinations to do their work properly. Some combinations are antagonistic, or work against each other while the action of others is enhanced when combined with certain other minerals and vitamins. Most minerals have multiple functions; while they may work alone in one instance, they cannot in another without assistance of other minerals or vitamins. For example, calcium requires sufficient vitamin D for its absorption. Calcium, in turn is essential for metabolizing iron. Too much calcium on one hand interferes with utilization of magnesium, manganese and zinc. High levels of calcium in the blood, accompanied by low levels of phosphorus results in reduced appetite and slow body growth. Large quantities of fats or lipids bind calcium and prevent its absorption; also contain a high content of fats/lipids, which not only destroy vitamin E but also bind calcium.

Without phosphorus, niacin may not be assimilated. Too much phosphorus creates an imbalance in the minerals and decreases calcium. Without magnesium; calcium, phosphorus, sodium, potassium and vitamin C may not be metabolized. Iron is also necessary for metabolizing the B

vitamins. Zinc is essential for protein synthesis. Copper is needed to convert the body's iron into hemoglobin, and is essential for the utilization of vitamin C. Selenium and vitamin E are synergistic. Both are antioxidants preventing or slowing down ageing and hardening of tissues through oxidation. Polyunsaturated fatty acids work against Vitamin A unless there are antioxidants such as selenium and Vitamin E present.

Lastly, micronutrients are different from macronutrients in that they do not supply direct energy. Rather, they work with the body to help extract energy from the foods we eat, in addition to helping ensure that our body functions optimally during everyday activities. Some of the tasks minerals perform include maintaining water balance; aiding absorption, digestion and transport of nutrients (Sehmi, 1993); transmitting nerve impulses, and regulating muscle contraction.

Therefore a well balanced diet providing adequate mix of both macro-and micronutrients is necessary for the well being and proper functioning of the body. In this study, a food supplement of a mix of both macro and micronutrients was used to address this aspect.

2. 7 Strategies for Improving Nutritional Status

Currently, the most widely used strategies for reducing macro and micronutrient deficiencies are supplementation, food diversification, and food fortification (Refer to operational definitions). Overall, studies suggest that increases in net daily energy and macronutrient intake can be achieved with oral supplements, and their use may be an effective means of maintaining or increasing intake for some patients.

Among these are studies showing slower disease progression in people with higher levels of nutrients overall, as well as studies that tie slow disease progression and/or improvements in various symptoms to supplementation with specific vitamins, minerals, amino acids or fatty acids. Some suggest an increased benefit from special oral preparations containing specific amino acids and proprietary agents for people with HIV infection (Suttmann *et al.*, 1996). However, nutritional supplementation should be provided alongside other relevant care to HIV.

Dietary counseling (FANTA, 2004; WHO/FAO, 2002; Piwoz and Preble 2000; Rabeneck , 1998) can help individuals identify target energy intake and food choices to suit individual tastes, practices, and tolerances; should emphasize the importance of maintaining energy intake, even during periods when eating is not pleasurable; and can give patients techniques for managing HIV or medication-related symptoms such as anorexia, early satiety, nausea, vomiting, diarrhea, food intolerances, and oral or esophageal ulcers. Because HIV-infected persons are at increased risk for food-borne infections, food safety is also an important component of dietary counseling.

2.8 Use of Antiretroviral drugs

Antiretroviral drugs directly attack the virus and significantly reduce the rate of replication of the virus in the body of the HIV infected person. These drugs decrease the viral load and slow down the progression of disease. Combining two or more of these drugs enhances efficacy, which is referred to as combination therapy or HAART. WHO, 2003b recommends four first-line HAART regimes for adults and adolescents in resource limited settings as shown below;

First-line HAART regimes for adults and adolescents

1. stavudine + lamivudine + nevirapine
2. zidovudine +lamivudine + nevirapine
3. stavudine + lamivudine + efivirenz
4. zidovudine +lamivudine + efivirenz

Source: WHO 2003b.

According to WHO, (2003b), a person begins ART when s/he meets any of the following three conditions:

- WHO stage 4 of HIV regardless of CD4 count
- WHO stage 3 of HIV with a CD4 count < 350/mm^3
- WHO stage 1 or 2 of HIV with CD4 count <200/mm^3

2.9 Nutrition and ARV Treatment

Efforts have begun for a significant scaling up of the use of antiretroviral drugs in settings such as sub-Saharan Africa where the epidemic has had its most devastating impact. However, questions have been raised about the use of ART against a background of health problems not often seen in the developing world (Shevitz and Knox, 2001; Piwoz and Preble, 2000). HAART improves nutritional status, independent of its effects on viral suppression and immune status (Rousseau *et al.*, 2000) although wasting still develops in some patients (Wanke *et al.*, 2000). Antiretroviral therapy has been shown in numerous studies to reduce the replication of HIV in the body, reduce the incidence of opportunistic infections and AIDS-related illness. ARV side effects such as nausea and vomiting may affect adherence to therapy particularly in the first months of treatment. This may be complex and relate to poor adherence to therapy, resistance of the virus or poor nutrition.

Optimal antiretroviral treatment requires safe, clean drinking water and a balanced diet rich in energy, protein and micronutrients. Secure good nutrition and clean water may make antiretroviral therapy easier to take and help ensure that treatment works effectively (FANTA, 2004; WHO/FAO, 2002).

2.10 Food and Drug Interactions

The presence of food in the gastrointestinal tract can influence the absorption of several HIV medications (FANTA, 2004). In addition, complicated medical and food schedules as well as side effects of the medications can compromise adherence to and tolerability of the regimen. Antiretroviral therapy influences nutritional status in different ways. Either directly by inducing a loss of appetite or indirectly through the side effects of the drugs which may inhibit the functioning of body organs e.g. the liver which may in turn reduce and or, block the breaking down and or absorption of certain nutrients into the body.

For example, the drug efavirenz should not be taken with any fatty food; stavudine decreases the absorption of several micronutrients especially with long term use. Rifampicin, a drug used to manage/treat TB as an opportunistic infection also interferes with the absorption of several micronutrients by the body (Kenya National Clinical Manual for ARV Providers, 2004). Some

ARVs may also act by promoting over absorption of specific micronutrients which results in toxicity. It is therefore important to know about these interactions so they can help patients with timing of their antiretroviral regimens with regard to food.

2.11 Gaps in Knowledge

Inability to eat food secondary to complicated medical regimes or fatigue adds to nutritional risk resulting in continued weight loss and wasting. Malnutrition can be reduced (WHO/FAO, 2002) by treating the immediate causes of the problem such as oral thrush, mouth sores, other infections and, providing foods that are soft and well tolerated by the infected person.

Although studies have been conducted and there is continued conflicting results; malnutrition and wasting remains common among HIV- infected patients on ARV treatment even in developed countries. An urgent need to develop and evaluate macronutrient supplementation for the improvement of the nutritional status for infected HIV people and the impact of nutritional supplementation (food/micronutrient supplementation) on people on ART was realized at a conference held in Durban by WHO, 2005.

Data are limited regarding the effect of ART on the nutritional needs of malnourished adults particularly in resource poor settings; in populations where there is already preexisting malnutrition/under nutrition. Besides, few studies also exist on the direct effect of dietary intake on various parameters (stage of disease, BMI and presence or absence of opportunistic infections) in HIV positive individuals. This study attempts to address these gaps through assessing the effect of food supplement on nutritional status and morbidity experience of malnourished HIV positive adults receiving ART in resource poor settings.

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CHAPTER 3

METHODOLOGY

3.1 Introduction

This chapter discusses the specific apparatus, techniques and procedures used for the collection of data in the study. The methods for statistical analysis of the data are also presented. The researcher supervised and coordinated activities and actively participated in the collection of nutrition data (anthropometry and dietary patterns).

3.2 Study Site

The study was conducted in three sites; Mathare North Health Centre which is within Mathare slum, in the Northeast of the city of Nairobi and; a home to about 400,000 people. Riruta city council situated South of the city of Nairobi and part of Kawagware area, and Maragua District hospital within Maragua District situated in Central Province, Southeast of Nairobi with a total population of 409,302 (CBS, 2001). All sites operated Comprehensive Care Clinic (CCC) and Voluntary Counseling and Testing Centers (VCT) from which eligible clients were recruited and enrolled into the study.

3. 3 Study Population

The study subjects were both male and female HIV positive adults (> 18 years old) visiting the health clinics and scheduled to begin ART treatment within five weeks or were starting ART on the day of enrollment into the study. The target group were wasted adults with a body mass index (BMI) of < 18.5; eligible for ART according to WHO (2003b) and Kenya National ART (NASCOP, 2002), guidelines.

3.4 Study Design

This was a two-arm randomized intervention study design conducted among malnourished HIV/AIDS adult clients on ART in 3 sites; Mathare North health centre, Riruta city council clinic and Maragua District hospital. The study group received daily food supplement but not the control group. However, both groups received the standard nutritional counseling for healthy eating offered at the health facilities. Each client was followed up for 3 months during the period of July 2006 and April 2007.

3. 5 Sample Size Determination

The sample size was computed using the formula below (Dohoo *et al.*, 2003).

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

Where:

n = sample size

Z = the value attributed to α and to 1-ß.

σ = assumed standard deviation of 1.77 kg/m²

1- ß = the power of the study at 90%

α = significant level (at 0.05)

$\mu_1 - \mu_2$= the expected difference in BMI that can be detected by sample to claim effect of supplementation = 0.75

Calculation;

$$n = \frac{(1.96 + 1.2816)^2 * 2(1.77)^2}{(0.75)^2}$$

= 117 clients

Plus 25% Attrition rate = 147 Clients in total.

3.6 Sampling Procedure

The clients were recruited from patients attending comprehensive care clinics (CCC) and enrolled for administration of ART and those referred from Voluntary Counseling and Testing Centers (VCT). The study sites were purposively selected so as to capture the total targeted sample size of 147 clients.

The clients who had a BMI <18.5 were purposively selected from all the patients who were on ART. They were then divided into qualified males and females respectively, and simple random sampling applied separately to each group; to allocate them into either food supplement or non food supplement group. This was to ensure that each client in each gender stratum had equal

chance of being allocated to either group. A schematic summary of the sampling is presented in Figure 2.

The sampling was similarly carried out in each site until the required total number of sample size was obtained. Those clients who were allocated to the food supplement group, were presented with a card for food collection, where nutritional counseling was also offered to all clients. The rationale for sampling from three different sites was so as to obtain the required total sample size within the short period of time available for the study. Originally, study clients were to be randomly selected from one site, but it became apparent that this was not feasible as client's enrollment into the study was low and additional sites were necessary to achieve the targeted sample size.

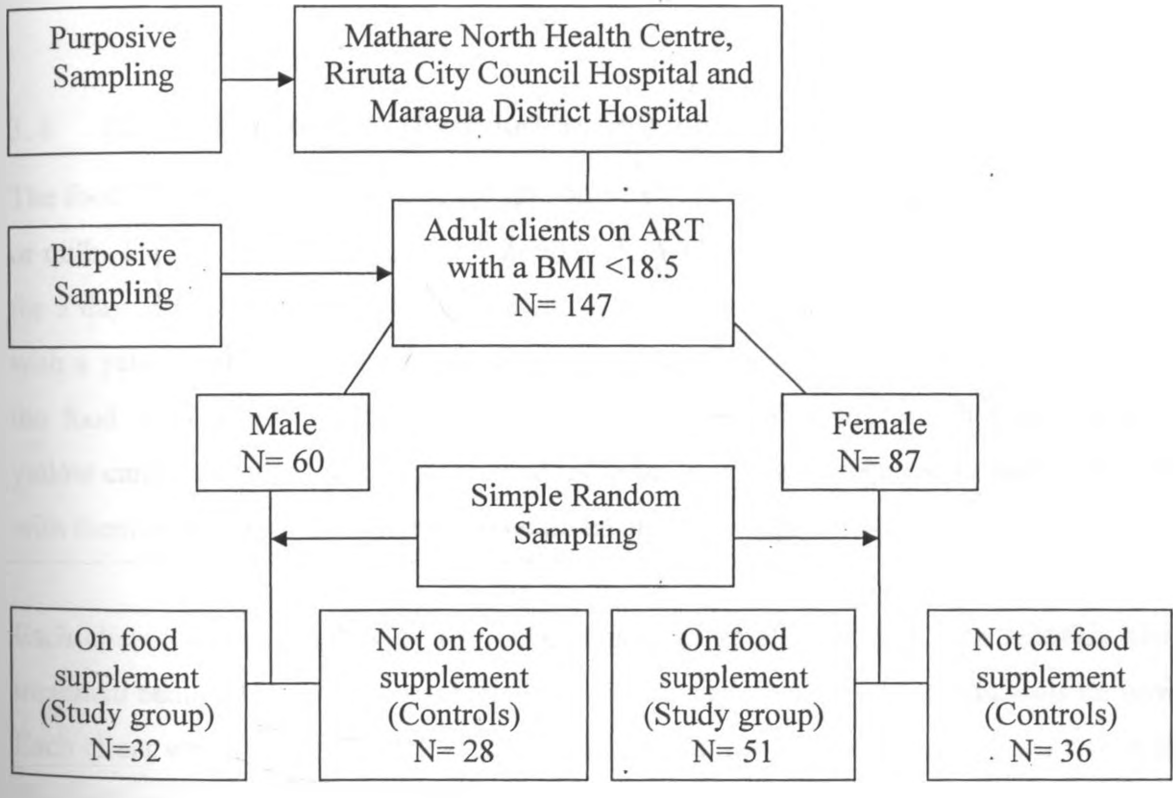

Figure 2: Schematic summary of the sampling procedure

3.7 The Food Supplement

The food supplement known as Insta Foundation, was produced by Insta Foods Kenya ltd, based at the Export Processing Zone (EPZ) in Athi River. It was a blend of maize, Soya, sugar, palm

oil, and micronutrients pre-mix composed of 45% of the total energy recommended daily intake by an adult in the symptomatic stage. In addition, the daily portion of 300g/day provided the following:-

Table 2: Percent RDA of energy and selected important nutrients

Nutrient	% of RDA	
	Women	Men
Energy	45	45
Protein	109	89
Vitamin A	49	49
Vitamin C	35	29
Vitamin E	216	216
Selenium	40	40
Iron	89	200
Zinc	100	73
Folate	38	38
Magnesium	161	125

3. 8 Administration of the Food Supplement

The food supplement was pre-cooked and only needed to be reconstituted using boiled hot water or milk. The food was packaged in a small sack carrying 15 packets of the 300g targeted supply for a day. The clients presented a card for the food during the first visit then they were issued with a yellow card. The client's number, date when the client was recruited and provided with the food supplement and the next date of visit in the following month were recorded in the yellow card each time the client received the food. They were required to carry the yellow card with them on the next visit in order to be given another supply.

Each client was provided with a months' supply (2 small sacks) at each monthly visit to the treatment centre. The food was labeled with the nutrient content and instructions on how to use. Each client was instructed on how to use the food and given strict instructions not to share the food with others in/out of the household. The clients were told the supplement was part of their daily medication to ensure that they consumed all the 300g per day. Every time the food supplement was issued, it was recorded in duplicate in a receipt book and a copy given to the client. At the end of each issuing day, the small sacks were counted and number remaining recorded. The supplies for each site were refilled at the end of each week.

3. 9 Data Collection

Using a pretested structured questionnaire, and with the help of trained data collection assistants, data were collected on demographic and socio-economic characteristics of the clients, anthropometry, morbidity experience, dietary patterns at the initial visit; and then data on anthropometry, morbidity experience and adherence to the supplement intake regime collected on subsequent visits with dietary patterns being collected on the 3rd month of follow-up. The methodologies employed in the data collection included review of literature and documents, observation and interviews of the 147 clients.

3.9.1 *Research instruments/tools*

Questionnaires were administered to 147 clients in collecting data on demographic and socio-economic characteristics (See appendix 2). Height meter, weighing scale, and non-stretchable MUAC insertion tape were used in obtaining anthropometric data. Surgical spirit and cotton wool were also used for sterilizing the MUAC tape after every use.

3.9.2 *Recruitment and training of research assistants*

A total of eight research assistants were recruited from among the staff in the participating facilities and trained. They were already employed in the facilities as community health workers, nutritionists or public health officers. The training covered explanation on the objectives of the study, sampling procedure, administration of the questionnaire, procedure to follow on anthropometric measurements and administration of the food supplement. The training which was standardized in all sites took one week.

3.9.3 *Pre-testing of study tools*

The questionnaire and the methodology used were pre-tested among CCC clients in all the study sites to ensure that the procedures worked and logistics were implemented. The numbers of clients pre-tested were 3, 4 and 3 in Mathare North Health Centre, Maragua District Hospital and Riruta City Council Hospital respectively. The pre-testing involved administering the questionnaire, sampling procedure, correct taking of the measurements and recording by the research team.

3.9.4 *Data collection procedures*

A pre-tested structured questionnaire was administered to each of the clients who were recruited on different days as they came for their clinic visits. Data were collected on, demographic and socio-economic characteristics of clients, anthropometry, morbidity experience, dietary patterns and adherence to supplement intake regime.

3.9.4.1 Anthropometric Measurements

Anthropometric measurements of height, weight and mid-upper arm circumference (MUAC) were obtained and body mass index (BMI) calculated. The height and weight measurements were taken after the clients had removed their shoes and any heavy clothing. Measurements were taken at baseline and monthly follow-ups for 3months and recorded in the questionnaire.

Height measurement

A height meter was used to measure the height of the clients. The client was asked to stand barefoot on a flat surface with heels together, arms to the side looking straight ahead; heels, buttocks, shoulder blades and back of the head if possible, against the vertical surface of the height meter. They were then asked to inhale, hold their breath and maintain an upright posture while the headboard was lowered on the highest point of the head; just before the measurement was taken. The measurements were read with the eye level on the headboard; to the nearest 0.1cm. Two readings were made for each client and average calculated. The two readings were used when the difference between them was less than 0.5cm.

Weight measurement

The weighing scale was placed on a flat, hard surface. The pointer of the scale was then adjusted to 0 reading. Each client was asked to stand still on the scale with the body weight equally distributed on both feet; and wearing light clothing and without shoes. The reading was taken only after the pointer had stopped wobbling. The weight was then read to the nearest 100g (0.1kg) and recorded. Two measurements were taken for each patient and the average calculated.

In case there was a difference of more than 0.5kg then a third reading was taken, and an average of the two closest readings taken and recorded. .

Mid-upper arm circumference (MUAC) measurement

A non stretchable MUAC insertion tape was used to measure the mid-upper arm circumference (left upper arm, the point between the tip of the shoulder and the elbow) of the clients. The tape was sterilized with surgical spirit after each client was measured. The readings were recorded in centimeters. This was done using the following (Cogill, 2003) steps;

- The tip of each client's shoulder was located using fingertips.
- Elbow was then bent to make a right angle.
- The tape was placed at the tip of the shoulder and while the other side pulled down straight towards the elbow. It was then bent up to the middle length to estimate the midpoint.
- The client's arm was straightened and the MUAC tape wrapped around the arm at midpoint.
- The tension on the arm was checked to ensure that it was neither too tight nor too loose around the arm.
- The measurement seen in the middle of the slot was recorded to the nearest 0.1cm.

3.9.4.2 Morbidity Experience

The morbidity experience was assessed using a structured questionnaire to determine the health status of the clients. Common ailments and symptoms (Poor appetite, Metallic taste in the mouth, Nausea, Vomiting, Constipation, Abdominal pain, Oral thrush, Ulcers, Difficulty swallowing, Fatigue, Cough, Fever, Diarrhea and Skin rashes) among HIV positive people were listed in the questionnaire. The client was requested to state the ailments s/he had experienced during the last 30 days. The examination was performed at baseline and after every month for 3months by a registered clinical officer.

3.9.4.3 Dietary Patterns

A dietary intake count of 14 food groups consumed by the client was administered using a structured questionnaire at baseline, and after 3 months. The dietary diversity information was

elicited by using a simple count of food groups in the previous 24-hour period. For every food group consumed, a score of "1" was allocated then a dietary diversity score was calculated.

The study used 14 food groups to measure individual dietary diversity as recommended by FAO, (2007) namely: 1) Cereals, 2) Vitamin A rich vegetables and tubers, 3) White tubers and roots, 4) Dark green leafy vegetables, 5) Other vegetables, 6) Vitamin A rich fruits, 7) Other fruits, 8) Organ meat, 9) Flesh meats, 10) Eggs, 11) Fish, 12) Legumes, nuts and seeds, 13) Milk and milk products 14) Oils and fats.

3.9.4.4 Adherence to Supplement Intake Regime

Adherence was assessed at each follow up by asking and checking the remaining supplement in order to find out if the supplement was consumed daily and whether or not it was shared.

3.10 Research Clearance and Ethical Considerations

The larger research project had been approved by the Kenya Medical Research Institute scientific steering and Research Ethical Review Committees. This component of the study was covered by the approval/ethical clearance given to the larger project. The clients consented through a consent form (Appendix 3), after the purpose and procedures of the study were explained. All clients participated in the study voluntarily.

3. 11 Data Quality Control

Training on data collection; importance of completeness and accuracy in reporting was conducted. Equipment were carefully calibrated and standardized before each measurement. Data collection and handling were closely monitored and supervised throughout the study period to ensure completeness.

3. 12 Data Management and Analysis

The completed questionnaires for each day were examined in the field for completeness and consistency of answers. The principal investigator kept the completed questionnaires until they were processed in the computer.

Data were entered, cleaned and analysed using Statistical Package for Social Sciences (SPSS) version 12.0 and excel. Analysis involved descriptive statistics: means and standard deviations for continuous data; proportions and their 95% confidence intervals and frequency distributions for categorical data. Further analysis of data involved use of Analysis of variance (ANOVA), t-tests and Chi-square to test for significant differences at p value <0.05 and relationships among groups of variables. Nutritional status was categorized as follows:

MUAC;

- Men- MUAC<22.4cm (Severe malnutrition), MUAC 22.4-23.1cm (Mild malnutrition), MUAC 23.2-24.3cm (Moderately malnourished), MUAC>24.3cm (Normal) (WHO, 1995).
- Women- MUAC<21.4cm (Severe malnutrition), MUAC 21.4-22.1 (Mild malnutrition), MUAC 22.2-23.2 (Moderately malnourished), MUAC>23.2 (Normal) (WHO, 1995).

BMI;

- BMI<15.9 Kg/m^2 (Severe underweight), BMI 16-16.9 Kg/m^2 (Moderately underweight), BMI 17-18.49 Kg/m^2 (Mild underweight), BMI>18.5 Kg/m^2 (Normal) (WHO, 1995).

The body mass index for each client was computed by dividing weight in kilograms by height in metres squared. Individual dietary diversity score for each client was computed as the sum of the number of food groups consumed by an individual client over the 24 hour recall period out of 14 food groups (FAO, 2007).

CHAPTER 4

RESULTS

4.1 Introduction

This chapter presents the study results including demographic and socio-economic characteristics, nutritional status (weight, MUAC, BMI), dietary intake patterns, morbidity experience and adherence to the food supplement. The total sample size (147 clients) was obtained from 3 sites; Mathare North Health Centre-57 clients, Riruta City Council-20 clients and Maragua District Hospital-70 clients.

4.2 Demographic and Socio-economic Characteristics

4.2.1 Demographic characteristics

Table 3 below presents the distribution of demographic characteristics of the study clients. A larger proportion of the clients participating in the study were female. The majority of the study clients were between the ages of 30-39 years. The mean age of the clients in the food group and control group was 35.3 (±8.9) and 35.0 (±6.7) respectively; no significant difference was found in the mean age between the two groups using the t-test.

Most of the clients were in monogamous marriage and either had an education level of between standard 5-8 or college, while a small proportion had university education. Household size ranged from 1 to 12. The modal household size was one while the mean size was 4.3 (±9.5) and 2.9 (±2.0) for the food supplement and control group respectively. Overall, the mean household size was 3.7 (±7.3). There was no significant difference in the mean household size between the two groups.

Table 3: Percent distribution of study clients by selected demographic characteristics

Characteristics		Food supplement group (n=83)	Control group (n=64)	Total (N=147)
		%	%	%
Gender	Male	38.6	43.8	40.8
	Female	61.4	56.3	59.2
Age (yrs)	20-29	32.5	21.9	27.9
	30-39	33.6	54.8	42.8
	40-49	25.2	20.5	23.3
	50+	8.4	3.1	6.2
Marital Status	Single	21.7	14.1	18.4
	Married (monogamous)	33.7	45.3	38.8
	Married (polygamous)	4.8	4.7	4.8
	Separated	12.0	10.9	11.6
	Divorced	10.8	12.5	11.6
	Widowed/widower	13.3	12.5	12.9
	Cohabiting	3.6	-	2.0
Education Level	None	8.4	4.7	6.8
	Standard 1-4	8.4	9.4	8.8
	Standard 5-8	54.2	50.0	52.4
	Form 1-4	9.6	10.9	10.2
	College	15.7	23.4	19.0
	University	3.6	1.6	2.7
Household Size	1-3	56.7	70.3	62.6
	4-6	36.1	25.0	31.2
	>6	7.2	4.7	6.2

4.2.2 Income and occupation of the study clients

Table 4 shows the percent distribution of study clients by their income and occupation status. Among both groups, casual/informal labor, farming, formal employment, and small businesses played important roles as main sources of household income. However, X^2 test revealed a statistically significant difference (p=0.000) in the percent distribution of clients by main source of income between the two groups. While more of the clients in the food supplement group relied on casual labor and remittances/NGO support, more of the controls relied on farming, formal employment and small businesses as household main sources of income. Similarly, there was a significant difference in the employment status between the clients in the food group and the control group (p=0.000). A larger proportion of the clients in the food supplement group compared to control group were unemployed, housewives or in skilled employment, while a larger proportion of the clients in the control group compared to clients in food supplement

group were in unskilled employment, self employed or farmers. Overall, unskilled employment was the main occupation of the clients, followed by unemployment, farming, self employment, house wife and skilled employment. These differences were not expected to negatively affect the results as the supplemented group seemed worse off.

Table 4: Percent distribution of study clients by HH main source of income, occupation and HH income levels

Characteristics		**Food supplement group (n=83)**	**Control group (n=64)**	**Total (N=147)**
		%	**%**	**%**
*HH main source of Income**	Casual/ Informal labor	33.7	25.0	29.9
	Formal employment	16.9	18.8	17.7
	Farming	19.2	29.7	23.8
	Small business	14.5	17.2	15.7
	Remittances/NGO support	14.5	9.4	12.3
*Occupation**	Employed unskilled	27.7	32.8	29.9
	Employed skilled	7.2	4.7	6.1
	Business self employed	12.0	15.6	13.6
	Farmer	14.5	18.8	16.3
	Housewife	8.4	6.3	7.5
	Unemployed	26.5	18.8	23.1
HH monthly income	< 5000	60.0	59.4	59.8
	5000 - < 10000	26.5	28.1	27.2
	≥ 10000	7.2	9.4	7.5

* χ^2 test significant difference $p<0.05$

However, there was similar distribution of household income between the study group and controls, whereby almost two-thirds of the clients earned Ksh <5000 (≈73USD), one-quarter earned Ksh. 5000 – 10000 (USD 73 to 146) and less than one-tenth earned ≥10,000 (≥ USD 146) per month.

4.2.3 Household food source and food expenditure

Table 5 shows majority of households purchased their food from the market; one third got their food from household farms with a small proportion receiving food from relatives, welfare or NGOs. The daily household food expenditure spent by two-thirds of the clients was ≈ 1.50 US dollar while less than 10% of the clients spent 3 USD.

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Table 5: Percent distribution of households by main food source and food expenditure

Characteristics		Food supplement group (n=83) %	Control group (n=64) %	Total (N=147) %
Source of Food	Purchase	65.1	60.9	63.3
	Household farm	26.5	35.9	30.6
	Relatives/Welfare/NGO	4.8	1.6	3.4
	Other	3.6	1.6	2.7
*Daily HH Food Expenditure**	< 100	61.4	56.3	59.2
	101-201	30.1	32.8	31.3
	> 201	6.0	9.5	6.9
	Don't know	2.4	1.6	2.8

* *1$=68Kshs*

4.2.4 Main source of water

Table 6 shows the main source of water for domestic use for the majority of the clients was tap water. One-quarter of the clients sourced their water from wells/boreholes and a small proportion used pond water. Chi square test revealed a significant difference (p-value=0.032 at 95% CI) in the source of water, between the groups with more of the food supplement group using tap water and more controls using well/borehole. Almost two thirds of the clients treated their drinking water by using chlorine.

Table 6: Percent distribution of clients by HH domestic water source, mode of water treatment

Characteristics		Food supplement group (n=83) %	Control group (n=64) %	Total (N=147) %
Source of water	Tap water	69.9	53.1	62.6
	Well/Bore hole	20.5	31.3	25.2
	Pond water	2.4	4.7	3.4
	Rain water	7.2	10.9	8.8
Water treatment	Yes	62.7	56.3	59.9
	No	36.1	42.2	38.8

4.2.5 Distance to health facility

Table 7 shows that two-thirds of the clients from the food supplement group lived within 10Km from the target health centre while over half in the control group lived within 10-19Km. One quarter lived more than 20Km away particularly those in the food supplement group. There was no significant difference in the distances.

Table 7: Percent distribution of clients by distance to health facility

Characteristics		**Food supplement group (n=83) %**	**Control group (n=64) %**	**Total (N=147) %**
Distance to Health Facility (Km)	< 10 Km	66.3	56.2	61.9
	10 - 19	4.8	20.8	11.6
	More than 20	25.3	18.8	22.4
	Don't Know	3.6	4.7	4.1

4.3 Nutritional Status

Table 8 shows the anthropometric measurements of the respondents at both baseline and after 3 months for the client groups. At baseline, there was no significant difference in weight and BMI between the groups. However, the mean MUAC for the food supplement group was coincidentally, significantly lower than the non food supplement group at baseline (p=0.037).

Both groups showed a significant ($p < 0.05$) increase in weight, MUAC and BMI after 3 months of follow-up. There was no significant difference in the weight and MUAC between the two groups after 3months, but there was a significant difference (p-value=0.019) in BMI at end of follow-up.

This implied that although there was no significant difference between the groups in the absolute weight, the MUAC among the food supplement group increased such that the significant difference observed at baseline was no longer present and BMI became significantly higher among the food supplement group than the control group at end of follow-up.

Therefore the increase in MUAC and BMI was greater among the food supplement group than among the control group.

Table 8: Anthropometric characteristics of the study group

Indicator	Food supplement group (mean ± SD)		Control group (mean ± SD)	
	Baseline	After 3months	Baseline	After 3months
*Weight (Kg)***	44.89 ±7.14	50.76 ±7.40	45.61 ±6.06	48.98 ±6.89
*MUAC (cm)**	21.35* ±2.39	23.40 ±2.21	22.16* ±2.25	23.16 ±2.07
*BMI Kg/m²)***	16.77 ±1.37	19.01* ±1.74	17.02 ±1.25	18.31* ±1.83

*t-test significant difference $p<0.05$; **t-test significant increase after 3 months $p<0.05$

Figure 3 below shows the trend in the mean weight of both client groups from baseline through to 3 months of follow up. The food supplement group had a steady upward increase in weight while in the control group the weight after 2nd month through to 3rd month was stagnant.

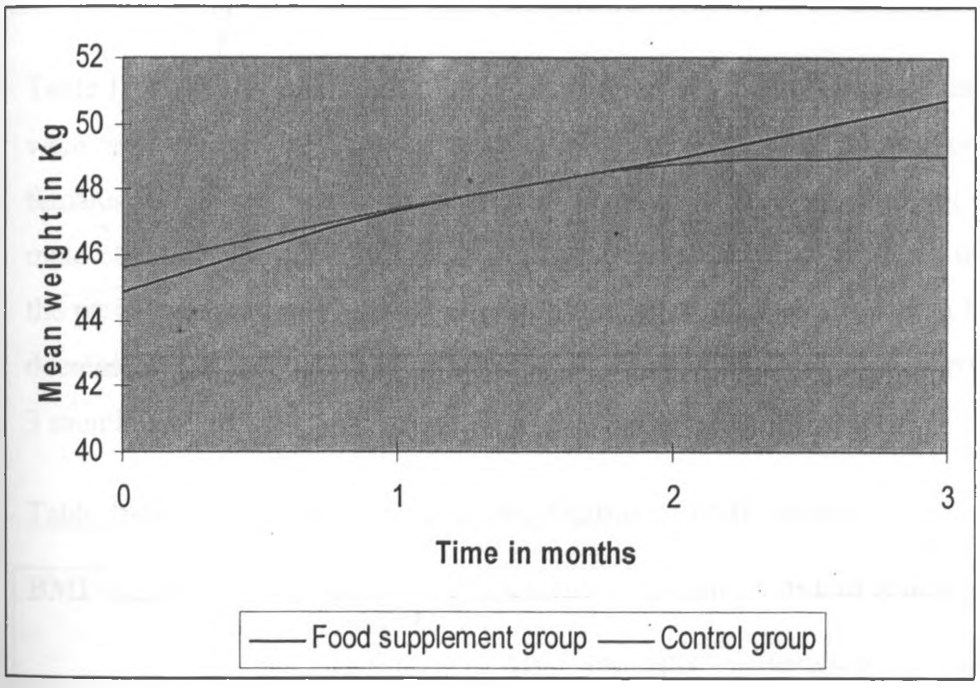

Figure 3: Trend in mean weight by study group

4.3.1 Nutritional status by Sex

Table 9 shows that more than half of male and about two thirds of female clients on food supplement group were severely malnourished at baseline but after 3 months, these proportions decreased to less than a quarter. In the control group, the decrease in the proportion of severely malnourished men and women after three months was small. It is worth noting that there was also an increase in the proportion of men and women with normal status in both groups.

Table 9: Percent distribution and classification of clients according to MUAC and sex

MUAC (cm) by sex	Food supplement group (n=83) %		Control group (n=64) %	
	Baseline	After 3months	Baseline	After 3months
Males				
< 22.4	53.1	21.9	35.7	25.0
22.4 - 23.1	10.6	12.5	21.4	21.4
23.2 - 24.3	12.8	15.6	32.2	21.5
> 24.3	12.5	50.0	10.7	32.1
Females				
< 21.4	60.8	19.6	38.9	30.6
21.4 - 22.1	3.9	11.8	5.5	8.3
22.2 - 23.2	19.6	21.5	19.5	8.3
> 23.2	15.7	47.1	36.1	52.8

Table 10 shows that more than one-third of female and less than one-tenth of male clients were severely underweight at baseline but after 3 months, the proportion decrease in females was more than in males. After 3 months, about two-thirds of both female and male clients in the food supplement group had normal BMI while in the control group; the percentage increase of both clients with normal BMI was less than half. There was a decrease in the proportion of moderately and severely underweight men and women after 3 months.

Table 10: Percent distribution and classification of BMI and sex

BMI (Kg/m^2)	Food supplement group (n=83) %		Control group (n=64) %	
	Baseline	After 3months	Baseline	After 3months
Males				
< 15.9	6.8	6.2	17.9	10.0
16 - 16.9	34.0	-	25.1	7.1
17 - 18.49	59.2	28.1	57.0	50.0
> 18.5	-	65.7	-	32.9
Females				
< 15.9	35.0	2.0	22.0	11.2
16 - 16.9	15.9	13.8	16.8	14.0
17 - 18.49	49.1	19.8	61.2	30.8
> 18.5	-	64.4	-	44.0

4.4 Dietary Patterns of the Study clients

Table 11 shows the 24-hr mean individual dietary diversity score for food supplement group and the control group at baseline and after 3 months. The number of food groups consumed at baseline was less than after 3 month in both groups. After 3 months of nutritional counseling, the study clients increased their consumption of diverse foods resulting in the improvement of their nutritional and morbidity status.

The 24-hr IDDS was significantly higher for food supplement group at baseline and after three months p=0.04 and p=0.03 respectively. The IDDS increased in both groups between baseline and after 3 months. The increment in each group was highly significant p=0.000.

Table 11: Mean dietary diversity score of the clients

Time	**Food supplement group (n=83) (mean ± SD)**	**Control group (n=64) (mean ± SD)**
IDDS (Baseline)	6.35±2.65	5.58±1.82
IDDS (After 3months)	7.02±1.76	6.36±1.90

Table 12 below shows the percent distribution of study clients by the type of food groups consumed within the previous 24hour period. There was a significant difference (p-value=0.015 at 95% CI) in the consumption of Vitamin A rich vegetables and tubers, and eggs at baseline between the groups. More clients on food supplement consumed Vitamin A rich vegetables and eggs than the clients not on food supplement. However, this changed after 3 months and there was no significant difference between the two groups. The proportion of clients consuming legumes, nuts and seeds was significantly higher among the food supplement group than the control group after 3 months.

Table 12: Percent distribution of the food groups among the clients

Food Group	Food supplement group (n=83) %		Control group (n=64) %	
	Baseline	After 3months	Baseline	After 3months
1. Cereals	91.6	84.3	85.9	82.8
2. Vitamin A rich vegetables and tubers	31.3[a]	34.9	14.1[a]	34.4
3. White tubers and roots	42.2	57.8	31.3	45.3
4. Dark green leafy vegetables	50.6	68.7	54.7	62.5
5. Other vegetables	69.9	71.1	64.1	64.1
6. Vitamin A rich fruits	22.9	27.7	17.2	20.3
7. Other fruits	65.1	75.9	59.4	71.9
8. Organ meat (iron rich)	4.8	6.0	4.7	1.6
9. Flesh meats	22.9	20.5	23.4	18.8
10. Eggs	31.3[a]	19.3	14.1[a]	15.6
11. Fish	7.2	8.4	17.2	9.4
12. Legumes, nuts and seeds	54.2	55.4[b]	46.9	40.6[b]
13. Milk and milk products	71.1	83.1	64.1	82.8
14. Oils and fats	71.1	88.0	62.5	85.9

[a/b] χ^2 test significant difference $p<0.05$

Foods that were mostly consumed by the clients were; cereals, milk and milk products, oils and fats, other vegetables, other fruits and dark green leafy vegetables. Foods that were least consumed were; organ meat, fish and eggs.

4.5 Effect of Adherence to Supplement Regimen on Nutritional Status

Table 13 below shows 91% cases ate the food supplement daily and 31.1% of them shared the supplement with their families. The mean MUAC, weight and BMI of the clients who had adhered to the supplement was significantly higher than in those who did not adhere (t-test p=0.03; p=0.02; p=0.000 respectively). Table 12 and figure 5 show mean weight, MUAC and BMI was lower among those who did not eat daily compared to those who ate daily. Further more, among those who ate daily, weight and BMI was lower among those who shared the supplement than among those who did not share the supplement.

Table13: Mean MUAC, Weight and BMI by adherence to supplement regime

Adherence to the food supplement regime		**Food supplement group (N=83)**		
		MUAC	**Weight**	**BMI**
Eat food supplement daily? (N=83)	Yes (n=76)	23.47±2.09*	51.29±7.26*	19.11±1.52*
	No (n=7)	19.33±2.08	39.40±3.83	15.33±1.71
Shared food? (N=76)	Yes (n=25)	24.04±1.97	50.50±5.51	19.05±1.72
	No (n=51)	23.16±2.10	51.64±8.04	19.15±1.45

* χ^2 test significant difference p<0.05

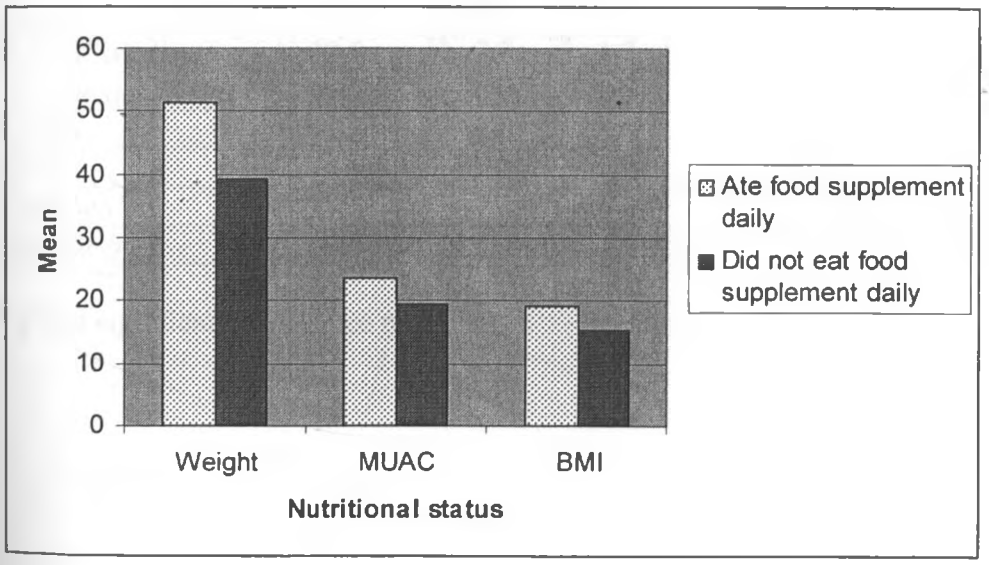

Figure 4: Mean nutritional status by adherence to supplement regime

4.6 Morbidity Experience

At baseline, (Table 14) majority of the clients from both groups experienced poor appetite, coughs, fatigue but not vomiting. There was significant difference (p=0.044 and p=0.016 at 0.05 level) between both groups in those who experienced fever and skin rash after 1 month respectively. These morbidity experiences decreased monthly and at month 3, most ailments were not being experienced except in the food supplement group where a few clients vomited while others had oral thrush.

Table 14: Percent distribution of clients by monthly morbidity experience and study group

Symptoms	**Food supplement group (n=83) %**				**Control group (n=64) %**			
	Baseline	**1st**	**2nd**	**3rd**	**Baseline**	**1st**	**2nd**	**3rd**
Poor appetite	41.0	10.8	9.6	-	37.5	17.2	7.8	-
Metallic taste in the mouth	25.3	4.8	1.2	-	20.3	12.5	-	-
Nausea	25.3	10.8	6.0	-	21.9	15.6	4.7	-
Vomiting	-	3.6	1.2	14.5	1.6	1.6	-	-
Constipation	14.5	10.8	1.2	-	17.2	7.8	4.7	-
Abdominal pain	16.9	6.0	1.2	-	10.9	7.8	4.7	-
Oral thrush	20.5	4.8	-	8.4	18.8	1.6	-	-
Ulcers in the mouth	8.4	8.4	1.2	-	15.6	4.7	4.7	-
Painful swallowing	12.0	7.2	1.2	-	18.8	4.7	3.1	-
Fatigue/tiredness	37.3	16.9	10.8	-	42.2	23.4	18.8	-
Cough	41.0	10.8	4.8	-	46.9	15.6	3.1	-
Fever	14.5	7.2[a]	7.2	-	25.0	17.2[a]	7.8	-
Diarrhea	20.5	7.2	4.8	-	17.2	3.1	-	-
Skin Rash	20.5	9.6[a]	7.2	-	17.2	23.4[a]	10.9	-

[a] χ^2 test significant difference $p<0.05$

CHAPTER 5

DISCUSSION

5.1 Demographic and Socio-economic characteristics

Demographic and socio-economic characteristics affect food availability and the nutritional quality of food which in turn affects nutritional and morbidity status of HIV positive individuals. The finding that more than half of the clients involved in the study were adult women aged between 20-49 years is in agreement with reports that majority of HIV infection in Sub-Saharan Africa is among women in their prime of productivity (UNAIDS/WHO, 2007). Women commonly provide care and are mostly involved in food production. Therefore high infection of women in their prime productivity implies jeopardization of food production and household food security.

The finding that most of the clients had some formal education with a small percentage never attending school is in agreement with (National figure 7%) KDHS, (2003). Household food security often depends on adequate income and assets, including land and other productive resources. A majority of households with people living with HIV and AIDS are chronically food insecure (MoH, 2007). The main sources of household income among both groups are casual/informal labor, farming, formal employment, and small business. However, while clients in the food supplement group rely on casual labor and remittances/NGO support, more of the controls rely on farming, formal employment and small businesses as their main sources of income implying that the food supplement group started worse off than the control group. The low level of education among the study group may have resulted in the high percentage of unemployment and unskilled employment, hence a low monthly household income and high food insecurity. Furthermore, HIV and AIDS is known to reduce a household's productive labor, income and food stores, undermining food security.

In Kenyan towns, 22.8% of the population lives below the $1 poverty line (CBS, 2007) per person per day. Two-thirds of the clients spend less than one hundred Kenya shillings a day on household food expenditure. This implies reduced food availability and low nutritional quality of food incase it is available in the households since this has to be shared amongst four persons living in the same household.

The main source of water for domestic use is easily accessible to both groups. However, majority of the clients in the food supplement group source their water from the tap while the control group source their water from well/borehole and rain water. Safe drinking water is very important, particularly in HIV infected households due to the risk of food and water- related infections (FANTA, 2004), usage of chlorine by majority of the clients to treat their drinking water is commendable as this helps to make the water safe. In general, the study group have access to safe, clean drinking water (treated with chlorine) and the counseling on food preparation, safety and hygiene supports improvement of nutritional and morbidity status in both groups.

5.2 Effect of Nutritional Counseling and Supplementation on Anthropometric and Morbidity Status

Adequate nutrient intake in the absence of infections results in appropriate anthropometric indices including BMI and MUAC. Therefore, nutritional intervention is thought to be important to maximize the gain in body mass. Some studies suggest an increased benefit from special oral preparations containing specific amino acids and proprietary agents for people with HIV infection (Suttmann et al., 1996). High-energy, high protein oral supplementation combined with nutritional counseling resulted in an overall weight gain of 2.2 Kg (Stack et al., 1996). In a 3-month study of patients with AIDS wasting, the glutamine-antioxidant supplement increased body mass of 1.7Kg, whereas the control group gained 0.4Kg (Shabert et al., 1999). Not every nutritional regime is found to be effective. Immune-enhancing oral formulas consumed daily for 1year did not appear to have any differential effect on weight or immune status (Keithley et al., 2002). Similarly, multivitamin and minerals supplement containing peptides and triglycerides did not increase body cell mass (Gilbert et al., 1999). The significant increase in mean MUAC, weight and BMI in both the food supplement and non food supplement group implies an improvement in nutrient adequacy and infection status of the clients in both groups. It is however, important to note that at baseline; mean weight, MUAC and BMI of the non food supplement group were greater than in the food supplement group. After 3 months of follow-up, the increment observed was more in the food supplement group than the non food supplement group. The implication in these findings is that food and nutrition counseling contributed to the

improvement in the nutritional status in both groups, but only to a certain threshold, after which food supplementation took over in the food supplement group.

This is supported by the increase in dietary diversity experienced in both groups after 3 months of nutrition counseling. At baseline, higher percentage of the food supplement group were severely malnourished than in the non food supplement group but after 3 months there was an increase in the percentage of clients within the normal MUAC category for both groups. However, the increment was greater in the food supplement group. The observed weight, MUAC and BMI cannot be attributed solely to increase in food intake since it is known that this factor alone does not improve the nutritional status of the clients (Izquierdo et al., 2000; FANTA, 2004; Piwoz and Preble, 2000).

Therefore, dietary counseling has potential for improving nutritional status among HIV infected individuals on ART. It can give patients techniques for managing HIV medication-related symptoms such as anorexia, nausea, vomiting, diarrhea and oral thrush among others. In this present study, clients on food supplement have reduced opportunistic infections. The food supplement enabled clients to regain their appetite and sense of taste while reducing oral thrush, nausea and ulcers in the mouth, which is relevant in the reversal of malnutrition (Keusch and Farthing, 1990; Piwoz and Premble, 2000). Nevertheless, the results indicate that counseling without access to diverse foods/sources of the nutrients is not enough. It can only contribute to a limited extent. This is especially true in resource poor communities who may have knowledge on how to improve their diets but are constraint by lack of resources that can empower them to access quality diet.

HIV infections are known to cause decreased food intake, malabsorption, (Keusch and Farthing 1990) increased utilization and excretion of nutrients thus resulting in weakened immune syster and poor nutritional status. Good nutrition can prevent and treat many of the opportunisti infections and relieve the symptoms associated with them, which include coughing, feve itching, and difficulty in swallowing; and diarrhea. At baseline, both groups had presented wit various opportunistic infections. However, the significant decrease in the percentage of clien experiencing all the symptoms except those of vomiting and oral thrush in both groups may b due to the improved nutrient intake and nutritional status. According to Macallan et al., (199 opportunistic infections seem to be a prime determinant in weight loss, though weight recove

is still possible with successful treatment of infections. Nutrition counseling alone and when combined with oral nutritional supplements may have influenced this positive health outcome after 3 months (Rabeneck, 1998). Nutritional counseling given to both groups aided in the better management of opportunistic infections hence enhancing the utilization of the antiretroviral drugs.

5.2.1 Adherence to supplement intake regime

For meaningful outcomes in supplementation studies, high levels of adherence to the supplement intake regime have to be observed. A small percentage did not fully adhere due to being either sick, not liking the taste of the food or skipping their previous visit, thus reducing the quantity of food consumed per day. The higher mean weight, MUAC and BMI among clients who adhered to the supplement intake regime than among those who did not adhere underscores the importance of appropriate monitoring of such nutrition studies. This is also reflected in their significantly increased nutritional status in this study, which also implies that the group full adhering to the supplement regimen was more advantaged than those not adhering.

5.3 **Dietary Patterns of the study clients**

Consumption of a variety of foods increases the diet quality of an individual and has been reported to also improve nutrient adequacy. Knowledge learnt from nutrition counseling should continuously be applied for importance of good nutrition. The study clients were made aware of their special nutritional needs thus applied the new knowledge and modified their diets accordingly. However diet diversification is determined by availability and economic access of food to the individual or households (FANTA, 2004). With the majority of the clients in this study spending less than $1 on food per day, they are unable to adequately diversify their diet. It is no wonder that consumption of animal proteins and iron rich foods among the clients is low. In resource poor settings, a high proportion of people living with HIV and AIDS are food insecure and do face additional obstacles to following nutritional recommendations while some households experience periodic food insecurity.

Seasonality also affects food availability especially fruits and vegetables. During lean seasons, some foods become more expensive than others and access depends on purchasing power. The study clients have different occupational status while some are casual laborers, others are

farmers. Farmers have an advantage since better options are available to them such as increasing production of nutrient rich crops in addition to animals both as source of food and income. Rarely do they lack food as compared to casual laborers. During low rainfall, farmers have better access to food unlike casual laborers who depend on each day's wage which does not guarantee food security. Some of the options available to improve food security for people with HIV and AIDS include; diet diversification and improved access to appropriate paid labor (MoH, 2007).

Nutrition counseling may have helped the clients identify food choices that were available, accessible and affordable to them and resulted in the significant increase in the consumption of diverse foods in both the study group. This contributed towards the improvement of consumption of vitamin A rich vegetables and tubers within the study group. However, the increment was larger in the non food supplement group than the food supplement group, and this may be due to a larger proportion of the clients in the non food supplement group being farmers' thus have easier access to diverse foods than those in the food group, who are mainly casual laborers.

CHAPTER 6

CONCLUSION AND RECOMMENDATION

6.1 Conclusion

This study assessed the effect of food supplementation on MUAC, body weight, BMI and morbidity experience of HIV infected adults receiving antiretroviral therapy. The design comprised of two groups, both of which received nutrition counseling but one also received food supplement for 3 months. Weight, MUAC and BMI increased in both groups after three months, but the increment in MUAC and BMI was higher among the food supplement group than the counseling only group. In addition, there was a decrease in the incidence of various morbidity experiences in both groups. Dietary diversity improved to a similar extent in both groups.

Therefore, we conclude that nutritional counseling alone has potential for improving the nutritional status, morbidity experience and dietary diversification of HIV infected adults on ART. Nevertheless, in resource poor communities, nutritional counseling alone can only impact positively to nutritional and morbidity status to the extent that the clients are able to economically access quality diet. We also conclude that food supplementation impacts positively on nutritional and morbidity status. Therefore, while nutrition counseling impacts positively on nutritional and morbidity status, the effect is even better when coupled with food supplement in resource poor communities.

6.2 Recommendation

It is clear from results that a majority of HIV infected adults on ART are unemployed and spend less than a dollar on food. They are unlikely to meet their RDI or nutrients on their resources. The clients need to be empowered to access food to ensure sustainability when food supplement is withdrawn. This study recommends the following:

- Sensitizing and strengthening nutrition education programmes at community level aimed at improving dietary consumption and nutritional management of opportunistic infections.
- Effort be directed towards integrating programmes that economically empower the clients and improve livelihoods (resource base) with nutrition care in order to ensure food

security. Meanwhile, food supplementation should be incorporated (and) or continued for malnourished HIV infected people on ART until their nutritional status and resource base improves.

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APPENDIX 1: Energy and nutrient density of food supplement and DRI for women and men infected with HIV

Nutrient	Instant Foundation 300g/day	DRI Woman (HIV+)	DRI Man (HIV+)
Energy(kcal d-1)	1360	3022	3022
Protein (g.d-1)	50	46	56
Calcium (mg.d-1)	258	1000	1000
Phosphorus (mg.d-1)	1050	700	700
Magnesium (mg.d-1)	500	310	400
Potassium (mg.d-1)	1700	4700	4700
Selenium (ug.d-1)	22	55	55
Zinc (mg.d-1)	8	8	11
Copper (mg.d-1)	2.9	0.9	0.9
Iron (mg.d-1)	16	18	8
Vitamin A (ug.d-1)	340	700	700
Vitamin C (mg.d-1)	26	75	90
Vitamin D (ug.d-1)	6	5	5
Vitamin E (mg.d-1)	32.5	15	15
Niacin (mg.d-1)	13	14	18
Folic Acid (ug.d-1)	153	400	400
Thiamine (mg.d-1)	1.3	1.1	1.2
Riboflavin (mg.d-1)	0.8	1.1	1.3
Vitamin B_6 (mg.d-1)	1	1.3	1.3
Vitamin B_{12} (ug.d-1)	0.5	2.4	2.4

APPENDIX 2: QUESTIONNAIRE

Effect of food supplementation on nutritional status (weight, mid-upper arm circumference and body mass index) of HIV infected adults receiving antiretroviral therapy in Kenya

Instructions: Read the following questions below carefully and fill in the blank spaces; where choices are given, circle the correct answer.

A: GENERAL INFORMATION Questionnaire number _____

Name of client _____ Date of interview___/___/___

Study site _____ Name of interviewer _____

Group _____

B: DEMOGRAPHIC AND SOCIO-ECONOMIC CHARACTERISTICS

1. How old are you? _____

2. Sex/Gender of the client? 1. Male 2. Female

3. What is your current marital status?
   1. Single 2. Married (monogamous)
   3. Married (polygamous) 4. Separated
   5. Divorced 6. Widowed/widower 7. Cohabiting

4. What level of education have you finished?
   1. None 2. Standard 1-4
   3. Standard 5-8 4. Form 1-4
   5. College 6. University

5. What is your main occupation?
   1. Employed unskilled 2. Employed skilled
   3. Business 4. Farmer
   5. Housewife 6. Unemployed

6. What is the amount in Kenyan Shillings of income for your household?
   1. < 5000 2. 5000-<10000
   3. ≥10000

7. What is the main source of income for your household?
   1. Casual/Informal labor 2. Formal employment
   3. Farming 4. Small business
   5. Remittances/NGO support

8. How many people do you live with in your household? _____

9. What is the main source of food for your household?
   1. Purchase
   2. Household farm/garden
   3. Relatives/Welfare/NGO
   4. Other _____

10. How much money in Kenyan Shillings do you usually spend per day in buying food? _____

11. What is the main source of your domestic water?
   1. Tap water
   2. Well/borehole
   3. Pond water
   4. Other _____

12. Do you usually treat water for drinking? 1. Yes 2. No

13. How far is your house from this health centre?
   1. Within 5 Km
   2. 5-9.99 Km
   3. 10-14.99 Km
   4. 15-19.99 Km
   5. More than 20 Km

C: ANTHROPOMETRIC ASSESSMENT

Measurement	**1st Reading**	**2nd Reading**	**Average**
14. Height (cm)	_____	_____	_____

Measurements / **Time**	**15. MUAC (cm)**			**16. Weight (Kg)**		
	1st Reading	**2nd Reading**	**Average**	**1st Reading**	**2nd Reading**	**Average**
Baseline						
1st month						
2nd month						
3rd month						

D: MORBIDITY EXPERIENCE

Have you experienced any of the following symptoms/diseases? 1. No 2. Yes

Time / Symptoms/diseases	Baseline	1st month	2nd month	3rd month
17. Poor appetite				
18. Metallic taste in the mouth				
19. Nausea				
20. Vomiting				
21. Constipation				
22. Abdominal pain				
23. Oral thrush				
24. Ulcers				
25. Difficulty swallowing				
26. Fatigue				
27. Cough				
28. Fever				
29. Diarrhea				
30. Skin rashes				

E. ADHERENCE TO FOOD SUPPLEMENT

31. Have you been eating the food supplement daily? 1. Yes 2. No

1st month _____ 2nd month _____ 3rd month _____

32. If not, what is the reason?

1st month _____

2nd month _____

3rd month _____

33. Have you shared the food with anyone? 1. Yes 2. No

1st month _____ 2nd month _____ 3rd month _____

34. If yes, who is the person you share the food supplement with?

1. Spouse
2. Own child (ren)
3. Neighbor
4. Friend

F: DIETARY DIVERSITY QUESTIONNAIRE

Please tell me the foods you ate from yesterday morning till today morning. Yes=1, No=0

Food Groups	**Baseline**	**After 3months**
1. Grain foods(Cereals)		
2. Tubers and vegetables rich in Vitamin A		
3. White roots and tubers		
4. Dark green leafy vegetables		
5. Other vegetables		
6. Fruits rich in vitamin A		
7. Other fruits		
8. Organ meats		
9. Other meat/Flesh meat		
10. Eggs		
11. Fish		
12. Legumes, Nuts and Seeds		
13. Milk and Milk products		
14. Foods made with Fats and Oils		

Source: FAO, 2007

APPENDIX 3: CONSENT FORM

Effect of food supplementation on nutritional status (weight, mid- upper arm circumference and body mass index) of HIV infected adults receiving antiretroviral therapy in Kenya

Principal Investigator: Aska Akumu Okumu

Sponsor: FANTA project through collaboration with Kenya Medical Research Institute (KEMRI) and Applied Nutrition Programme (ANP) of University of Nairobi

Location: Mathare north health centre, Riruta city council hospital and Maragua District hospital.

Introduction

You are being asked to participate in this research study which is trying to assess the effects of food supplementation on malnourished HIV infected individuals in Kenya. Currently, there is no national evidence to show whether provision of food supplements to persons on ART will improve their nutritional status and clinical response to treatment. Evidence from several studies has shown that counseling alone may not be sufficient.

Your decision to be in this study is voluntary and that you are free to withdraw your consent/discontinue participation in the research at any time.

Objective of the study

The objective of this research is to assess the effect of food supplementation on nutritional status and morbidity experience of malnourished symptomatic HIV infected adults receiving ART.

Participation in the study

If you agree to be in this research study, you will be asked detailed questions regarding yourself and health. You will be in this study for about three months. About 147 clients on ART will be enrolled in this study. This information will enable us provide you with good health care during the study period as well as assist in assessing changes resulting from ART treatment and food supplementation. You will be asked questions concerning your dietary habits and measurements of your weight, mid-upper arm circumference and calculation of your BMI recorded monthly. You will receive nutrition counseling and support on weight management, and dietary related symptoms. You may also have some questions regarding your rights as a participant; the study staff at the center can help you contact the right person to answer any questions you have.

Procedure

All clients who agree to participate in this study will have a 50:50 chance of getting the food supplement through randomization; that is, to pick only one piece of paper among several pieces which shows whether or not you will be given the food supplement or not. The food supplement comes already pre-cooked in powder form. It can be made into porridge and contains corn, soy, vegetable oil, sugar, vitamin premix and whey protein which is a dairy product.

Possible risks and discomfort

There are no known risks to you from taking part in the study though; in rare cases, clients may be allergic to ingredients in the food product. The product contains whey protein, which is a dairy product.

Benefits

All tests performed as part of the study will be provided free of charge. You will have client monitoring and follow-up for monthly clinical and nutritional assessment performances. Apart from this, by serving as a subject, you will help us learn more about how well the food supplement is working among HIV infected individuals and how well to benefit HIV subjects in future.

Costs

There are no charges for the study visits or the food supplement. Though, for other care that is not part of the study, you may continue to get standard health care at the centre at your own cost.

Confidentiality

All of the information obtained from you during the research will be kept confidential. However, the sponsor will analyze and evaluate the results of the study. The information may also be used to meet the reporting requirements of governmental agencies. The results of this research study may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

Please read the following information carefully:

If you agree to the above stated conditions and are willing to participate in the experiment, you may sign below and keep the copy of this agreement for future reference. By signing the form, you confirm that:

- You are at least 18years of age.
- You have carefully read the above consent form, understood it and agree to it.
- You want to participate in the above mentioned experiment.

STATEMENT OF CONSENT

I have read the information in this consent form. All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

Participant's Name	Participant's Signature or mark	Date
_____	_____	_____

I have explained the purpose of the study to the participant. S/He has read the form and was given the chance to ask questions, accepted the answers, and signed to enroll in the study.

Principal Investigator's Name	Principal Investigator's Signature	Date
_____	_____	_____