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Impacts of a Therapeutic Food Supplement Support Program on Nutritional and Health Outcomes in HIV/AIDS Patients

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by

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DEDICATION

This dissertation is dedicated to my light and my salvation, Jesus Christ, who in His infinite knowledge has orchestrated the circumstances to bring this work to completion. You are the source of my strength. May this achievement bring you glory.

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ABSTRACT

Previous studies have suggested that therapeutic food supplement programs (TSFP) play significant roles in the management of adult wasting, especially in persons living with HIV/AIDS, and is effective in improving their health and nutritional status. This research examined the impacts of taking therapeutic food supplements on nutritional status, food security, disease stage, and health-related lifestyle characteristics of people living with HIV/AIDS who are under antiretroviral treatment **(**ART).

A total of 366 cases of HIV/AIDS diagnosed between February 2016 and February 2017 were identified from a hospital in Addis Ababa, Ethiopia. In this study only 24% of the subjects had access to the therapeutic food supplement program (TFSP). Subjects were aged 18 years or more, on ART, and resident in the study area for at least one year prior to the time of the study. Pregnant and breast feeding woman were excluded.

Data such as biochemical measures, ART drug type and initiation date, therapeutic food supplement (TFS) type and initiation date, and anthropometric measures were retrieved from the Hospital's paper and electronic data base. Additionally, each participant was interviewed to provide information on adherence to the TFS, lifestyle characteristics, socio-demographic characteristics, and food security status.

Results indicated that the majority of the TFSP participants were female (68.2%); younger adults aged between 30-49 years (74.8%), married (45%), less educated (high school diploma or lower levels of education - 95.6%), unemployed (62.5%), and had low monthly incomes (less than $45.00 US dollars - 76.1%). Approximately 88.7% percent of the TFSP participants and 69.1% of the Non-TFSP participants were food insecure. The percentage of severe malnutrition (BMI<16.0 kg/m^2) within the TFSP participants dropped from baseline

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(19.3%), to six months (8.0%), and twelve months (10.2%). There were no significant differences in CD4 cell count between the TFSP and Non-TFSP groups during the study periods. However, the percentages of TFSP participants whose CD4 cell counts were greater than or equal to 500cells/µl improved from 25.8% at baseline, to 52.2% at six months, and 53.3% at twelve months.

A randomized control trial, using larger sample sizes, is recommended to further investigate the impacts of TFSPs on nutrition and health outcomes of HIV/AIDS patients.

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LIST OF ABBREVIATIONS

ABC Abacavir

AIDS-Acquired Immune Deficiency Syndrome

ART- Antiretroviral Therapy

ART Antiretroviral therapy

ARV Antiretroviral

ATV Atazanavir

AZT Azidothymidine, also known as Zidovudine

CDC Centres for Disease Control and Prevention

CD4 - Cluster of Differentiation 4

DHS-Demographic Health Survey

FBP: Food by Prescription

EFV Efavirenz

ETB: Ethiopian birr (currency)

FSW- Female Sex Worker

HRQoL: Health-related quality of life

Hb Hemoglobin

HIV- Human Immune Deficiency Virus

LPV/r Lopinavir/Ritonavir boosted

MTCT- Mother to Child Transmission

NCASC- National Centre for AIDS and STD Control

NRTI Nucleoside Reverse Transcriptase Inhibitor

NtRTI Nucleotide Reverse Transcriptase Inhibitor

NNRTI Non-nucleoside Reverse Transcriptase Inhibitor

NSAIDs Non-steroidal Anti-Inflammatory Drugs

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NVP Nevirapine

OIs- Opportunistic infections

OARAC: Office of AIDS Research Advisory Council

PLHIV- person or people living with HIV

PMTCT Prevention of Mother-to-child Transmission of HIV

RUTF Ready-to-use Therapeutic Food

QoL: Quality of Life

3TC Lamivudine

TDF Tenofovir Disoproxil Fumatrate

TFS: Therapeutic Food Supplement

TFSP: Therapeutic Food Supplement Program

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DEFINITION OF TERMS

Adherence: the extent to which a patient's behavior (taking medication, following a diet, modifying habits, or attending clinics) coincides with medical or health advice.

AIDS: the final stage of HIV infection

Anorexia: loss of appetite for food.

Anthropometrics: measure of the dimensions of the body and other physical characteristics. That is height, weight, mid-upper arm circumference and triceps skin fold.

Antiretroviral: A drug that suppresses the activity or replication of retroviruses such as HIV by interfering with the various stage of viral lifecycle.

Asymptomatic: not feeling symptoms or showing signs of disease or condition.

Body mass index (BMI): a measure of body weight for height that is calculated as weight in kilogram divided by height in meter squared.

Cluster Designation 4: a protein marker on the surface of certain types of T lymphocytes and other cells; HIV binds to CD4 receptors to enter host cells.

Food insecurity: the condition of not having physical or economic access to enough food to be productive and healthy.

HAART: (Highly Active Antiretroviral Therapy) a term for potent combination anti-HIV treatment, usually with three or more drugs from different classes.

Lean body mass: The mass of the body minus the fat (storage lipid).

Nutrition: Process by which living things acquire and utilize food for growth and maintenance.

Nutritional assessments: measurements of body size, body composition, or body function, intended to diagnose single or multiple nutrient deficiencies.

Nutritional status: The nutritional health of a person as determined by anthropometric measures, biochemical, clinical measures or dietary analysis.

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Opportunistic infections (OIs): is an infection caused by pathogens (bacteria, viruses, fungi, or protozoa) that take advantage of an opportunity not normally available, such as a host with a weakened immune system.

Quality of Life: an individuals' perception of their position in life in the context of their culture and value systems in which they live and in relation to their goals, standards, expectations and concerns"

Side effects: Secondary effect of a drug other than the reason it is prescribed. Side effects are usually related to negative effects. They are also called adverse events or drug toxicity.

Viral load: amount of viral genetic material (ribonucleic acid or deoxyribonucleic) acid in the blood or other tissues, often expressed as number of copies per milliliter.

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CHAPTER I: INTRODUCTION

Statement of the Problem

HIV infection is a global public health emergency and is most prevalent in areas of the world where undernutrition is also a serious concern. It is the 3rd top leading causes of death in Ethiopia (USDHHS 2016; WHO 2008).Food and nutrition security have been identified as issues that are critically interlinked with HIV/AIDS, and that need to be addressed along a continuum of prevention, treatment, care, and positive living (Catherine, 2006; Gardner 2007; Jones and Salazar, 2016). For diminishing susceptibility and vulnerability, and for improving prevention, treatment and care, and positive living interventions, food security (access and availability) is critical. Thus, there is the need for undertaking integrated food security and HIV/AIDS planning to better address the AIDS pandemic (Catherine, 2006; Chege et al. 2016).

In early 1981 the term AIDS exceptionalism - the idea that the disease requires a response above and beyond "normal" health interventions- is given to the trend to treat HIV/AIDS differently from other diseases, including other sexually transmitted, infectious, lethal diseases in law and policy (Smith and Whiteside, 2010). According to Colvin (2011), debates around health funding involve not only questions of which diseases should get what money, they also ask whether disease-based funding is the best way to spend the money. There are already intense debates around the best forms of health development financing in an era of large-scale antiretroviral therapy (ART).

In 2007, arguments against exceptionalism began to gain attention (Smith and Whiteside, 2010). The amount of funding allocated to HIV/AIDS was called into question, as were the types of programs being implemented. According to Smith and Whiteside (2010), England commentaries highlighted that many diseases and health issues such as under-nutrition, malaria, and respiratory disorders resulted in more deaths than those related to AIDS in many parts of the world, but were receiving less funding.

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Rather than focusing exclusively on HIV/AIDS ("AIDS exceptionalism"), it is more useful to think with an "HIV/AIDS lens" and thereby integrate a HIV/AIDS and food security approach from the inception stage of programming and policy development (Catherine, 2006).

Weight loss is common in HIV/AIDS infection. Through the reduction of intake, absorption and use of nutrients, and increased metabolism needs, HIV progressively weakens the immune system and impairs nutritional status (Ahoua et al., 2011). In turn malnutrition can exacerbate the effects of HIV by increasing susceptibility to AIDS-related illnesses (Ahoua et al., 2011). For living well, good nutrition must be part of the plan for people living with HIV/AIDS. There are many benefits to eating healthy foods. Some of the benefits of a well-balanced diet and lifestyle are that a balanced diet boosts the immune system, increases energy, builds and maintains muscle, helps to achieve and maintain a healthy weight, makes medications more effective, and reduces risks of other chronic diseases such as diabetes, heart disease and cancer (Pauline et al., 2010).

Persons or people living with HIV (PLHIVs) need a diet that provides all the essential nutrients to meet increased nutritional needs. Also, they require additional energy due to HIV, opportunistic infections, altered metabolism and nutrient malabsorption. Protein and fat requirements for HIV-positive persons are the same as those of healthy non-HIV-infected persons of the same age, sex, and physical activity level. Also, PLHIVs often suffer from micronutrient deficiencies, which potentially compromise their immune function and, in turn, their ability to fight infection (Gardner, 2007). PLHIVs that do not have sufficient food intake due to food insecurity should be provided food supplements to help cover their deficits (Gardner, 2007). According to Haile (2014), nutrition interventions like ready-to-use food therapy are critical components of a comprehensive response to the HIV pandemic.

WHO recommends that symptomatic HIV and AIDS patients to increase their daily energy intake by 50% from the requirements of normal active HIV negative adult of 2430 Kcal

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for male and 2170 kcal for female to keep proteins and vitamins and minerals intakes at normal daily requirement (Wagh and Deore 2014).

Effective interventions to integrate nutrition into the essential package of care, treatment and support for people living with HIV/AIDS are still lacking. Several pieces of evidence have been provided by different studies about the effectiveness of ready-to-use therapeutic food (RUTF) for treatment of acute malnutrition in HIV-infected (Sunguya et al., 2012). However, according to Bahwere (2009), and Ndekha et al. (2009) few data evaluating the effect of ready-to-use therapeutic food (RUTF) in HIV-infected, malnourished adults are available. Despite a seemingly remarkable progress on awareness about HIV, and access to ARV drug, problems regarding therapeutic food supplement remain underrepresented in Ethiopia. In a study conducted in Ethiopia, Maldey B, Haile F, Shumye A. (2014), from a total of 524 patients who received ready to use food therapy; 62.2% were recovered from malnutrition, 29.6% of patients didn't recovered, 5.9% defaulted from the food therapy and 1.9% had died. In another study, at Gondar University Hospital ART clinic, Ethiopia; a cross-sectional study was conducted in HIV positive children (age ≤ 18years; n=398; 62.6%) and adults (age >18 years; n=238; 37.4%) participating in the Ready-to-Use Therapeutic Food (RUTF) treatment program also reported that recovery rate from malnutrition were below 50% (Bhagavathula et al., 2016).

The causes for failure to recovery from malnourishment needs to be identified, characterized and quantitatively analyzed based on food security status, quality of life, age and gender based energy requirement, as well as other factors/barriers.

Purpose of the Study

The purpose of the proposed study was to investigate the impacts of taking therapeutic food supplements on nutritional status, food security, disease stage and health related lifestyle characteristics of people living with HIV and AIDS who are under ART. Additionally, the study

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was used to identify factors (reasons) that influence adherence to therapeutic nutrition supplements.

Research Questions

The main research question of this study was: "what roles do therapeutic food supplements play in addressing the challenge of nutritional status and health outcomes among HIV-infected individuals in Addis Ababa, Ethiopia?"

Sub-research questions were as follows:

(1) Are there differences in socio-demographic characteristics between TFSP and Non-TFSP participants?

(2) Was the therapeutic food supplement intake associated with body mass index (BMI), hemoglobin, and hematocrit in HIV-infected patients?

(3) Was the therapeutic food supplement intake associated with food security (as measured by the 6-item food security survey model) in HIV infected individuals?

(4) Was the therapeutic food supplement intake associated with disease stage (as measured by CD4 and viral load)

(5) Is there a difference in proportion of factors associated with adherence to TFS intake among TFSP participants?

(6) Is there a relationship between health related lifestyle characteristics (use of alcohol, illegal drugs, and smoking cigarette) and adherence of TFSP participation?

Hypotheses

The following hypotheses were tested:

(1) Subjects who are TFSP participants are more likely to be female, younger, married, less educated, unemployed, and have lower monthly incomes.

(2) There is a significant, positive association between therapeutic food supplement intake and BMI, hemoglobin, and hematocrit.

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(3) There is a significant, positive association between therapeutic food supplement intake and food security.

(4) Therapeutic food supplement receiving group will have significantly less advanced disease stage than the non-receiving groups.

(5) TFSP participants who are consumer of alcoholic beverages, illegal drugs, and cigarette are more likely to be non-adherents to TFS intake.

Significance of the Study

The findings on food security and nutritional status were expected to determine the impacts that therapeutic food supplements have on the nutrition and health status of people living with HIV/AIDS. It will also help nutrition counsellors to identify appropriate and possible nutrition actions at the center, in the implementation of the best nutrition actions. Improving nutrition will translate into better HIV management, which can lead to reduction in the cost of healthcare for the individual and the community. Further, it will assist policy makers in planning, implementation and decision making about appropriate food security programs for the HIV-infected population in Ethiopia.

The information obtained in this study will assist the Ethiopian Ministry of Health and other organizations in identifying and targeting those who need greater outreach efforts in order to maximize their access to therapeutic food supplements, and improve nutritional services and benefits to people living with HIV.

The data on disease stage and quality of life changes after initiation of therapeutic food supplements will help health care providers to understand the stage of HIV disease, and the effectiveness of therapeutic food supplement treatment, and make early intervention in case of any negative effects

It will also help identify barriers /factors that influence adherence to therapeutic nutrition supplement intake among HIV-infected patients.

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Also, the research outcome will help consumers, policy makers, nutrition supplement manufacturing industries, and others stakeholders that are working on HIV prevention identify which factors they should focus on to alleviate the barriers to adherence to therapeutic nutrition supplements intake.

The findings will assist in improving the quality of service delivery to individuals, groups' communities. Our research findings will also enable the development of a scientific data base that will be used in the nutrition and health industries.

As far as can be determined, there are currently no full-bodied published studies of the impact of a therapeutic food supplements support program on nutritional status and health outcome of HIV-infected adults receiving antiretroviral therapy in Ethiopia. This study will help provide additional information to bridge the knowledge gap and improve quality of patient care and treatment outcomes which is the current challenge in many ART programs. In addition, information gathered from this study will help screen and identify patients with a high likelihood of food insecurity, and susceptibility to AIDS-related illnesses so that they can be prioritized for tailored individualized treatment preparation and other interventions to improve treatment outcomes.

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CHAPTER II: LITERATURE REVIEW

Description of HIV/AIDS

Human immunodeficiency virus (HIV), is the virus that causes HIV infection (NIH, 2012). HIV attacks the immune system by destroying CD4 positive (CD4+) T cells, a type of white blood cell that is vital to fighting off infection. The destruction of these cells leaves people infected with HIV vulnerable to other infections. People who are not infected with HIV and generally are in good health have roughly 800 to 1,200 CD4+ T cells per cubic millimeter (mm^3) of blood. Some people who have been diagnosed with AIDS have fewer than 50 CD4+ T cells in their entire bodies. Acquired immunodeficiency syndrome (AIDS) is the most advanced stage of HIV infection (NIH, 2012).

The AIDS Epidemic in Ethiopia

HIV/AIDS was first recognized in the country in the mid-1980s, at about the same time as in other countries in the region. The first two cases of HIV infection in Ethiopia were reported in 1986 (HAPCO and GAMET, 2008). According to the Central Statistical Agency of Ethiopia and ICF International (2012), there were an estimated 793,700 people living with HIV of which 200,300 were children. The pediatric HIV population in Ethiopia consists mostly of older children who were vertically infected (infected by mother-to-child transmission/ perinatal infection) in earlier years when the coverage and effectiveness of Prevention of Mother to Child Transmission (PMTCT) in the country was low. According to the Central Statistical Agency report, in 2013 there were 163,800 HIV positive children aged 5-14 years old. In the same year, there were approximately 45,200 AIDS-related deaths, and about 898,400 AIDS orphans. The adult HIV prevalence was estimated at 1.5% in 2011, the year in which the last Ethiopian Demographic Health Survey (DHS) was conducted.

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However the prevalence varies according to age, sex, gender and geographical location. According to the 2011 DHS, the adult prevalence was almost twice as high among females compared to males at 1.9% versus 1.0% respectively. The distribution of HIV prevalence also varies by age, peaking earlier in females in the 30-34 years age group compared to 35-39 years in males. Among the younger age groups it can be seen that young women have a two- to six-fold higher HIV prevalence than young men aged 15-17 years (0% in males vs. 0.2% in females). In those aged 20-22 years, the prevalence was 0.1% in males vs. 0.6% in females (DHS 2011). A marked difference in the urban versus rural prevalence was reported, with urban areas showing a seven-fold higher HIV prevalence compared to rural areas (4.2% versus 0.6%).

The HIV epidemic in Ethiopia is becoming more concentrated in urban areas and along major transport corridors. DHS 2011 data show that the HIV prevalence in large towns, including Addis Ababa, the regional capital, increased from 2005 to 2011. The higher prevalence in Addis Ababa and large towns may be associated with labor migration to large urban areas and large scale construction projects as well as a growing service industry. The HIV prevalence in large towns, including Addis Ababa and the regional capital, is appreciably higher than that in rural areas, and the rate tended to be positively associated with the levels of population density. Squalid and crowded living conditions and relatively high rates of social interaction contribute to the maintenance and spread of HIV. Compared to rural areas, the urban population often engages in some form of high-risk behavior such as use of illegal drugs, and contacts with female sex workers. Moreover, a DHS 2011 analysis showed that the HIV prevalence is four times greater among populations that reside within 5 km from a main asphalt road compared to those further away (DHS, 2011).

Nutrition Education in HIV-infected Individuals

Nutrition education is an integral part of HIV care at any stage of the disease. It helps newly infected people to stay healthy, assists people taking antiretroviral drugs to manage their

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therapy, and allows people with end-stage AIDS to die with dignity (Nerad et al., 2003; Thapa et al., 2015).

Education and counseling are essential features of medical nutrition therapy for people living with HIV. Treatment of AIDS requires specialized knowledge in many areas, including nutrition (ADA, 2004). Nutrition-related issues that may require counseling include: (1) life style, for example physical activity level, basic nutrition concepts and habits, nutrition and food-related cultural behaviors, and ethnic beliefs; (2) Nutrition interaction; (3) Life skills and socioeconomic issues for example food and nutrition security issues (Pee and Semba 2010).

General education may include nutrition principles, physical activity, water supply safety, and food hygiene. Nutrition related symptoms and side effects could have a significant effect on dietary intake and ART adherence (Kremer et al., 2009). According to Siddiqui et al. (2007), nutrition-related side effects have been shown to correlate negatively with quality-of-life measures in people infected with HIV.

HIV/AIDS, Nutrition and Quality of Life

Quality of Life (QoL) of patient's is also important in a chronic disease patients like HIV and AIDS (Palermo, et al., 2013). According to Maluccio, et al., 2015, Health-related quality of life (HRQoL) is a comprehensive indicator of physical, mental, and social well-being that is associated with food insecurity and increasingly used to assess the well-being of people living with HIV/AIDS (PLHIV).

HRQoL can be affected by food and nutrition insecurity through different pathways, including chronic stress and nutritional status (Weiser et al. 2011). Food supply anxiety and uncertainty are indeed, key domains that are captured by our measure of food insecurity (Coates et al. 2007). Food insecurity is the predominant form of uncertainty experienced in daily living in Ethiopia and other countries in sub-Saharan African settings, especially among PLHIV (Hadle and Patil 2008). Given the centrality of resource limited settings, food insecurity may be strongly associated with daily and chronic stress (Hadle and Patil 2008). HRQoL outcomes would be

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negatively correlated with household food insecurity and positively correlated with diet quality (Palermo, et al., 2013).

HIV and Nutritional Status

Through reducing food intake, increasing energy requirements, and adversely affecting nutrient absorption and metabolism HIV was found to affect nutritional status. Inadequate nutritional intake may lead to poor nutritional status, decreased immunity and increased susceptibility to opportunistic infections (OIs), which can lead to further malnutrition. These in return speeds the disease progression, increases morbidity, and reduces survival time (Thapa et al., 2015). Wasting is one of the most visible signs of malnutrition as patients' progress from HIV to AIDS.

On the other hand appropriate food intake can help improve antiretroviral absorption and tolerance, improve quality of life (QoL) of PLHIV's (Thapa et al., 2015). For these reasons, nutritional support should be a fundamental part of a comprehensive response to HIV and AIDS (Charlene Porter 2006; Thapa et al., 2015).

Food insecurity is associated with decline CD4 counts, increased opportunistic infections, hospitalizations, and HIV-related mortality (Charlene Porter 2006). For PLHIV, good nutrition has been proven to increase resistance to infection, improve QoL, drug compliance, and drug efficacy (Charlene Porter 2006; Palermo, et al., 2013).

Household Food Security Status Measurement

Food security status can be measured using the Six-Item US Household Food Security Survey Module **(**Appendix D**).** This module and the associated Six-Item Food Security Scale were developed by researchers at the National Center for Health Statistics (USDA, 2012). If respondent burden permits, use of the 18-item U.S. Household Food Security Survey Module or the 10-item U.S. Adult Food Security Survey Module is recommended. However, in surveys that cannot implement one of those measures, the six-item module may provide an acceptable

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substitute. The Six-Item brief survey is preferred in order to decrease a participant's response burden, instead of the longer versions. Although it is short in length, it has been shown to measure food security and distinguish it from food insecurity with enough specificity, sensitivity and minimal bias compared to the original modules. Food security scores are coded and calculated using standard methods (USDA, 2012).

Responses of "often" or "sometimes" on questions HH3 and HH4, and "yes" on AD1, AD2, and AD3 are coded as affirmative (yes) **(**Appendix C)**.** Responses of "almost every month" and "some months but not every month" on AD1a are coded as affirmative (yes). The sum of affirmative responses to the 6 questions in the module is the household's raw score on the scale. Food security status is assigned as follows (USDA, 2012):

(1) Raw score 0-1—High or marginal food security (raw score 1 may be considered marginal food security, but a large proportion of households that would be measured as having marginal food security using the household or adult scale will have raw score zero on the six-item scale)
(2) Raw score 2-4—Low food security.
(3) Raw score 5-6—Very low food security.

For some reporting purposes, the food security status of households with raw score 0-1 is described as food secure and the two categories "low food security" and "very low food security" in combination are referred to as food insecure (USDA, 2012).

Public Health Impacts of Food Insecurity

According to Rosen et al. (2014), over the next decade the greatest improvements in food security are projected to occur in Ethiopia. Ethiopia's food security has improved markedly since the mid-1990s, when nearly all of the population was considered food insecure. Between 1995 and 2012, per capita food consumption increased more than 30 percent. Grains account for two-thirds of the country's diet and, since imports are very low, supplies depend on domestic

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production performance. Grain output has doubled over the last decade, with yield growth contributing more than area expansion in recent years. Over the next decade, this growth is projected to slow, but it will exceed the rate of population growth which, at about 2 percent per year, is lower than the regional average. As a result, food supplies, on a per capita basis are projected to rise and food security to improve. The share of the population that is food-insecure is projected to fall from 40 percent in 2014 to 20 percent in 2024 (Rosen et al., 2014).

Ensuring food security in Ethiopia households is a critical public health issue. Lack of access to adequate and nutritious food is associated with many negative health outcomes that span across a lifetime and influence future generations.

According to the U.S. Department of Agriculture (USDA) it is common for specific measures of food security to be defined as including both physical and economic access to food that meets individuals' dietary needs as well as their food preferences. Food security exists "when all people at all times have access to sufficient, safe, nutritious food to maintain a healthy and active life." (Coleman-Jensen et al., 2013). On the other hand, household food insecurity exists when the conditions of food security are not met, and members within a household report being hungry because of too little money for food, having to cut the size of meals because of too little money for food, or being unable to afford balanced meals.

According to Sell et al. (2010), poor nutrition affects the individual both physically and mentally. Poor nutrition resulting from food insecurity has been linked to experiences of behavioral problems in preschoolers. Infants born to mothers with inadequate nutrition before and during their pregnancy may experience developmental delays, low birth weight, congenital anomalies, and other health issues. Children who experience food insecurity are at increased risk of chronic health conditions, impaired academic development, as well as behavioral and social issues (Bryce et al., 2005; Darnton-Hill et al., 2004).

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FDA-Approved HIV Medicines and Treatment of HIV Infection

Treatment with HIV medicines is called antiretroviral therapy (ART). ART is recommended for everyone with HIV (FDA, 2016). People on ART take a combination of HIV medicines (called a HIV regimen) every day. A person's initial HIV regimen generally includes three HIV medicines from at least two different drug classes. Drug classes in this context are a group of drugs that share common properties, including a similar mechanism of action, chemical structure, or approved use. There are six major antiretroviral (ARV) HIV drug classes, grouped on the basis of how each drug interferes with the HIV life cycle. The six classes are as follows:

(1) nucleoside reverse transcriptase inhibitors (NRTIs);

(2) non-nucleoside reverse transcriptase inhibitors (NNRTIs);

(3) protease inhibitors (PIs);

(4) fusion and entry inhibitors;

(5) pharmacokinetic enhancers; and

(6) Integrase strand transfer inhibitors (INSTIs) (FDA, 2016).

ART, HIV medicines, help people with HIV live longer, healthier lives, but cannot cure HIV. HIV medicines also reduce the risk of HIV transmission.

Table 1 lists HIV medicines approved by the U.S. Food and Drug Administration (FDA) for the treatment of HIV infection. The HIV medicines are listed according to drug class and identified by generic and brand names (FDA, 2016).

Table 1: FDA-Approved HIV Medicines

Drug Class	**Generic Name** (Other names and acronyms)	**Brand Name**	**FDA Approval Date**

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Drug Class	Generic Name (Other names and acronyms)	Brand Name	FDA Approval Date
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)			
NRTIs block reverse transcriptase, an enzyme HIV needs to make copies of itself.	abacavir (abacavir sulfate, ABC)	Ziagen	December 17, 1998
	didanosine (delayed-release didanosine, dideoxyinosine, enteric-coated didanosine, ddI, ddI EC)	Videx	October 9, 1991
		Videx EC (enteric-coated)	October 31, 2000
	emtricitabine (FTC)	Emtriva	July 2, 2003
	lamivudine (3TC)	Epivir	November 17, 1995
	stavudine (d4T)	Zerit	June 24, 1994
	tenofovir disoproxil fumarate (tenofovir DF, TDF)	Viread	October 26, 2001
	zidovudine (azidothymidine, AZT, ZDV)	Retrovir	March 19, 1987
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)			
NNRTIs bind to and later alter reverse transcriptase, an enzyme HIV needs to make copies of itself.	delavirdine (delavirdine mesylate, DLV)	Rescriptor	April 4, 1997
	efavirenz (EFV)	Sustiva	September 17, 1998
	etravirine (ETR)	Intelence	January 18, 2008
	nevirapine (extended-release nevirapine, NVP)	Viramune	June 21, 1996

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Drug Class	Generic Name (Other names and acronyms)	Brand Name	FDA Approval Date
		Viramune XR (extended release)	March 25, 2011
	rilpivirine (rilpivirine hydrochloride, RPV)	Edurant	May 20, 2011
Protease Inhibitors (PIs)			
PIs block HIV protease, an enzyme HIV needs to make copies of itself	atazanavir (atazanavir sulfate, ATV)	Reyataz	June 20, 2003
	darunavir (darunavir ethanolate, DRV)	Prezista	June 23, 2006
	fosamprenavir (fosamprenavir calcium, FOS-APV, FPV)	Lexiva	October 20, 2003
	indinavir (indinavir sulfate, IDV)	Crixivan	March 13, 1996
	nelfinavir (nelfinavir mesylate, NFV)	Viracept	March 14, 1997
	ritonavir (RTV)	Norvir	March 1, 1996
	saquinavir (saquinavir mesylate, SQV)	Invirase	December 6, 1995
	tipranavir (TPV)	Aptivus	June 22, 2005
Fusion Inhibitors			
Fusion inhibitors block HIV from entering the CD4 cells of the immune system.	enfuvirtide (T-20)	Fuzeon	March 13, 2003

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Drug Class	Generic Name (Other names and acronyms)	Brand Name	FDA Approval Date
Entry Inhibitors			
Entry inhibitors block proteins on the CD4 cells that HIV needs to enter the cells.	maraviroc (MVC)	Selzentry	August 6, 2007
Integrase Inhibitors			
Integrase inhibitors block HIV integrase, an enzyme HIV needs to make copies of itself.	dolutegravir (DTG)	Tivicay	August 13, 2013
	elvitegravir (EVG)	Vitekta	September 24, 2014
	raltegravir (raltegravir potassium, RAL)	Isentress	October 12, 2007
Pharmacokinetic Enhancers			
Pharmacokinetic enhancers are used in HIV treatment to increase the effectiveness of an HIV medicine included in an HIV regimen.	cobicistat (COBI)	Tybost	September 24, 2014
Combination HIV Medicines			
Combination HIV medicines contain two or more HIV medicines from one or more drug classes.	abacavir and lamivudine (abacavir sulfate / lamivudine, ABC / 3TC)	Epzicom	August 2, 2004
	abacavir, dolutegravir, and lamivudine (abacavir sulfate / dolutegravir sodium / lamivudine, ABC / DTG / 3TC)	Triumeq	August 22, 2014
	abacavir, lamivudine, and zidovudine (abacavir sulfate / lamivudine /	Trizivir	November 14, 2000

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Drug Class	Generic Name (Other names and acronyms)	Brand Name	FDA Approval Date
	zidovudine, ABC / 3TC / ZDV)		
	atazanavir and cobicistat (atazanavir sulfate / cobicistat, ATV / COBI)	Evotaz	January 29, 2015
	darunavir and cobicistat (darunavir ethanolate / cobicistat, DRV / COBI)	Prezcobix	January 29, 2015
	efavirenz, emtricitabine, and tenofovir disoproxil fumarate (efavirenz / emtricitabine / tenofovir, efavirenz / emtricitabine / tenofovir DF, EFV / FTC / TDF)	Atripla	July 12, 2006
	elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide fumarate (elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide, EVG / COBI / FTC / TAF)	Genvoya	November 5, 2015
	elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate (QUAD, EVG / COBI / FTC / TDF)	Stribild	August 27, 2012
	emtricitabine, rilpivirine, and tenofovir alafenamide (emtricitabine / rilpivirine / tenofovir AF, emtricitabine / rilpivirine / tenofovir alafenamide fumarate, emtricitabine / rilpivirine hydrochloride / tenofovir AF, emtricitabine / rilpivirine hydrochloride / tenofovir alafenamide, emtricitabine / rilpivirine hydrochloride / tenofovir alafenamide fumarate, FTC / RPV / TAF)	Odefsey	March 1, 2016
	emtricitabine, rilpivirine, and tenofovir disoproxil fumarate (emtricitabine / rilpivirine hydrochloride /	Complera	August 10, 2011

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Drug Class	Generic Name (Other names and acronyms)	Brand Name	FDA Approval Date
	tenofovir disoproxil fumarate, emtricitabine / rilpivirine / tenofovir, FTC / RPV / TDF)		
	emtricitabine and tenofovir alafenamide (emtricitabine / tenofovir AF, emtricitabine / tenofovir alafenamide fumarate, FTC / TAF)	Descovy	April 4, 2016
	emtricitabine and tenofovir disoproxil fumarate (emtricitabine / tenofovir, FTC / TDF)	Truvada	August 2, 2004
	lamivudine and zidovudine (3TC / ZDV)	Combivir	September 27, 1997
	lopinavir and ritonavir (ritonavir-boosted lopinavir, LPV/r, LPV / RTV)	Kaletra	September 15, 2000

Source: (FDA, 2016)

Ready-to-Use Therapeutic Food (RUTF)

Ready-to-Use Foods (RUFs) are highly fortified, energy-dense pastes specifically designed for the treatment of malnutrition (Collins, 2016). RUFs are made from varying combinations of grains, pulses and seeds, milk powder, sugar, oil, vitamins and minerals. They are precooked and ready to eat straight from the pack (Collins, 2016).

Ready-to-Use Therapeutic Food (RUTF) is a mixture of nutrients designed to address the therapy of severe acute malnutrition without complications. Therapeutic foods are foods designed for specific, usually nutritional, therapeutic purposes as a form of dietary supplement. To improve and maintain better nutritional status for an HIV-positive individual, the World Health Organization (WHO) encouraged the use of Ready to Use Therapeutic Foods (RUTF) for community-based treatment of severe under-nutrition (Collins 2016; WHO, 2007; WHO, 2005).

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Broadly the food products (Nutraceuticals) are classified as dietary supplements & functional food & Beverages.

There are 4 types of RUTF are as follows:

(1) Ready-to-Use Supplementary Food (RUSF): targeting moderate malnutrition in children and adults. RUSFs are foods that are fortified with micronutrients as a remedy for malnutrition and can be consumed without cooking or the addition of water. RUSFs are formulated to supply all of the essential nutrients, both those required to maintain body function for normal growth. A deficiency of one or several of the functional nutrients impairs physiological or immunological function without any effect on anthropometric indices.

(2) Ready-to-Use Complementary Food (RUCF) – targeting chronic malnutrition among young children (under 5 years of age). Complementary foods, whether based on customary family foods or commercially manufactured complementary foods, tend to be bulkier than RUSFs. Although they may sometimes be fortified, they usually supply a smaller amount of fewer nutrients in a single meal. Many complementary foods need to be cooked (Anderson et al., 2001).

(3) Fortified Blended Foods (FBF): Fortified blended foods, such as corn/soy blend (CSB) and wheat/soy blend (WCB) have been provided as one of the sole fortified food assistance commodities among many different populations, and for a wide range of purposes, for the past 30 years or more. They consist of 20-25% soy, 75-80% corn or wheat, and a micronutrient premix. It is not a product well-adapted to meet the nutritional needs of young or moderately malnourished children because it contains a relatively large amount of anti-nutrients. It does not contain all the required nutrients (Menon et al., 2007).

(4) Ready-to-Use Therapeutic Food for HIV patients (RUTF-H) targeting acute malnutrition among HIV-infected adults. Studies in industrialized countries have demonstrated that

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weight loss is a good predictor of both opportunistic infection and death (Koyanagi et al., 2011). The WHO recommends that symptomatic HIV and AIDS patients increase their daily energy intake by 50% from the requirements of normal active HIV negative adults (2430 kcal for males, and 2170 kcal for females). Protein, vitamin and mineral intakes should be kept at normal daily recommended levels (Kosmiski, 2011).

Table 2 presents some nutrition and health benefits of therapeutic food supplements intake in HIV infected patients.

Table 2: Literature Review: HIV, Therapeutic food supplements Impact on Nutrition and Health Outcomes

Citation, Quality-rating Location	**Study-purpose** **Study Design Duration**	**Sample Size** **Age Gender Race/Ethnicity**	**Intervention/Exposure**	**Findings/Health outcomes**
Olsen et al. 2014 Positive Ethiopia	To determine the effects of lipid based nutritional supplements with either whey or soy protein in patients with HIV during the first three months of ART. Randomized controlled trial.	Initial n= 318 Final n = 281 Attrition=12. % ≥18years (Mean age 33 years) 66% female Not reported	Daily supplementation with 200 g (4600 kJ) of supplement containing whey or soy during either the first three or the subsequent three months of ART.	Participants receiving the whey and soy supplements had gained 0.85 kg (95% confidence interval 0.16 kg to 1.53 kg) and 0.97 kg (0.29 kg to 1.64 kg) lean body mass, respectively, more than controls. Lipid based nutritional supplements improved gain of weight, lean body mass, and grip strength in patients with HIV starting ART. Supplements containing whey

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	Three-Six months			were associated with improved immune recovery. Effects on immune recovery were not significant for the soy supplement.
Ndekha, Oosterhout, Saloojee, Pettifor, Manary 2009. Positive Malawi	To test the hypothesis that individuals on ART for 3 months with a greater BMI as a result of supplementary feeding with ready-to-use fortified spread would maintain a higher BMI 9 months after the feeding ended. Randomized controlled trial. 3 and 9 months of follow-up	Initial N= 336 Final N = 318 Attrition=5 % Not reported Not reported Not reported	Of the 318, 162 had received ready to-use supplementary food (RUFS) and 174 had received corn⁄soy blend (CSB)	Supplementary feeding with RUFS yielded a higher BMI in ART patients for the first 3 months and this study found that a higher BMI at 3 months confers a greater chance of survival 1 year after commencing ART; together these results suggest that supplementary feeding with RUFS for a period >3 months should be investigated, particularly for individuals with a BMI <18.5. A longer period of supplementary feeding in individuals with low BMIs may be beneficial.
Ndekha et al. 2009	To investigate the effect of two different food supplements	Initial n= 477 Final n = 439 Attrition=7.7	245 patients received Ready-to-use fortified spread and 246 patients received corn-	After 14 weeks of nutritional intervention and ARV therapy participants who

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Positive Malawi	on BMI in wasted Malawian adults with HIV who were starting ARV therapy. Randomized, investigator blinded, controlled trial. 15 months	% ≥18years Not reported Not reported	soy blend.	received Ready-to-use fortified spread had a greater increase in BMI, fat-free body mass, and mid-upper arm circumference than those who received corn-soy blend. No significant differences in the CD4 count, HIV viral load, assessment of quality of life, or adherence to antiretroviral therapy were noted between the two groups.

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Sunguya et al., 2012 Positive Tanzania	To examine the association between RUTF use with underweight, wasting, and stunting statuses among ART-treated HIV-positive children. Cross-sectional 2 Months	Initial n= 219 Final n = 219 Attrition=0 % ≥5 years Not reported Not reported	Out of 219 HIV positive children 140 (63.9%) had received the RUTF intervention. RUTF Plumpy nut is given to children with severe wasting or underweight or both severe wasting and underweight. Such children are treated With (dose) 200 kilocalories per kilogram per day until they reach the target weight, which should be in 6 to 10 weeks.	This study found that RUTF treated HIV-positive children under ART had lower proportions of underweight and wasting compared to RUTF naïve HIV-positive children under ART.

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CHAPTER III. METHODOLOGY

Study Area Background

Ethiopia is a country located in the horn of Africa. According to United Nations (UN) reports, Ethiopia is categorized as one of the least developed countries. Poverty remains a challenge, even though sustainable long-term economic growth; the socio-economic landscape of the country has made significant developments in the last decade. Ethiopia has registered double digit economic growth rates continuously in the past eight years (CSA, 2012). The level and distribution of poverty is declining from time to time and a remarkable economic growth has been observed (CSA, 2012).

The study was conducted in Addis Ababa, the capital city of Ethiopia. According to the 2007 Census the Addis Ababa City has a total population of 2,738,248 with a growth rate of 2.1 percent per annum (an additional 57,503 people per year). From the total population, 48 percent are males and 52 percent are females (CSA, 2007).

According to DHS 2011, the HIV epidemic in Ethiopia is becoming more concentrated in urban areas and along major transport corridors. DHS 2011 data show HIV prevalence in large towns including Addis Ababa the regional capital increased from 2005 to 2011. The higher prevalence in Addis Ababa and large towns may be associated with labor migration to large urban areas and large scale construction projects as well as a growing service industry. Moreover DHS 2011 analysis showed the HIV prevalence is four times greater among populations that reside within 5 km from a main asphalt road compared to those further away. HIV prevalence in Ethiopia, by region is shown in Figure 1.

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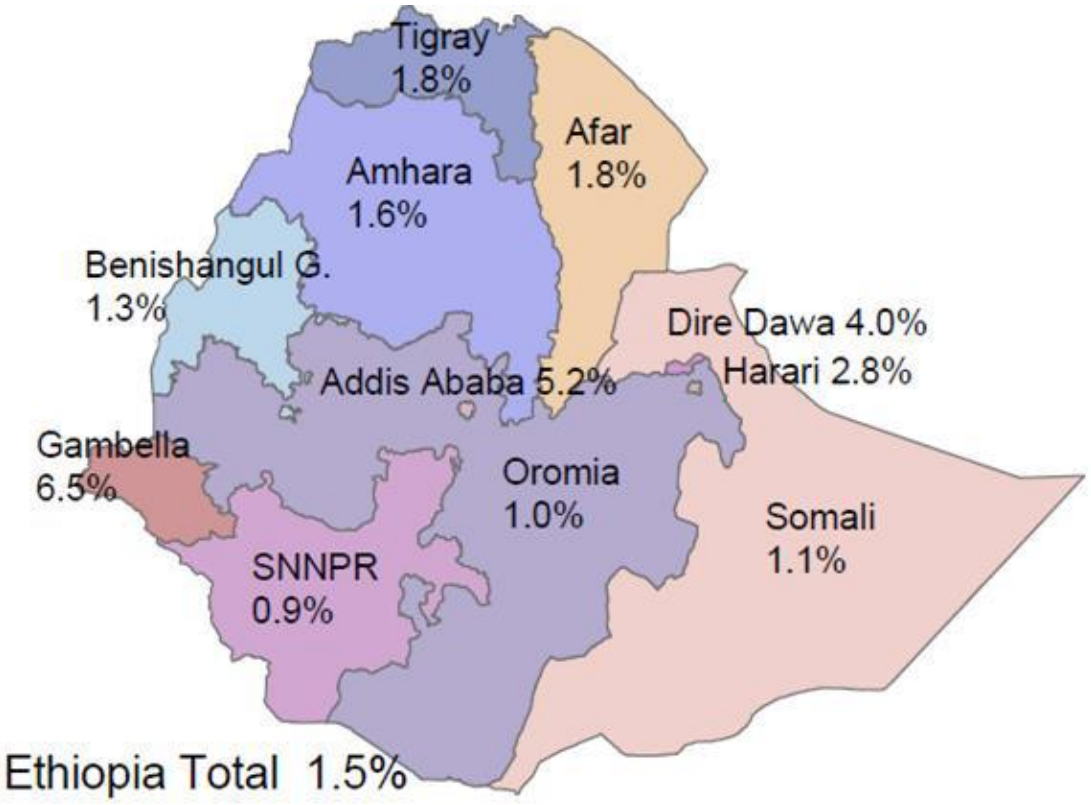

Figure 1: HIV prevalence by region, DHS 2011

Study Design

This retrospective observational study was conducted in St. Paul's Hospital, Addis Ababa, Ethiopia in collaboration with the Department of Nutritional Sciences, Howard University, Washington DC, USA. The study used patients' medical records and charts.

Existing service users of the ART drug from ART treatment center who were diagnosed with HIV infection and conformed to the inclusion criteria of the study were recruited. Control groups were those who are taking only ART drug, whereas the exposed group are those who were taking both the ART drug and Therapeutic food supplements. Participants (exposed group/recipients of therapeutic food supplement) and non-participants (non- recipients of therapeutic food supplement) of the therapeutic supplement, participants and non-participants of counseling and support program, and good cooperation.

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This study was conducted from February 2016 to February 2017. The detailed project timeline is presented at Appendix A.

Human Participants

This study was approved by the Institutional Review Board (IRB) of the Howard University Washington, DC; and the St. Paul's Hospital, Addis Ababa, Ethiopia. Participants included in the study were recruited from the St. Paul's Hospital. This Hospital provides healthcare services to all patients including the HIV infected individuals in Addis Ababa.

Participants were considered eligible if they were HIV positive, aged 18 years or more, on ART, and resident in the study area for at least one year prior to the time of the study. HIV positive subjects, who had not lived in the study area for a minimum of 12 months, pregnant and breast feeding woman, were excluded in this study. In the case of HIV/AIDS affected individuals, those whose status was not clearly known to Health Workers were not considered as affected, to avoid speculation.

Convenience sampling was applied by searching subjects' medical records on the computer databases (Master patient chart book) of St. Paul's Hospital, Addis Ababa with a timeframe of twelve months.

After signing informed consent, subjects were recruited from St. Paul's Hospital, Addis Ababa, Ethiopia. The nurse in charge explained the objectives of the study to the participants in order to use their service record including socio-demographic data, current services used, ART drug and Therapeutic food supplements intake records, follow up record, biochemical and anthropometric measures, life style characteristics and quality of life from the computer database (patients' charts) for analysis. There was no loss in follow up due to the retrospective nature of the study.

All data collected from the subjects were kept confidential. No name, addresses, or other identifiable information were associated with the data in any way. The data were kept in a locked

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file cabinet in the principal investigator's office. Only the principal investigator and student investigator had access to the data.

Procedures

Three hundred and sixty-six cases of HIV and AIDS diagnosed between February 2016 and March 2017 were identified from St. Paul's Hospital Registry, Addis Ababa, Ethiopia. Of the data collected in patient's chart the following variables were utilized: date of confirmed HIV+), ART drug (initiation date, ART drug type), therapeutic food supplement intake (initiation date, therapeutic_supplement type, adherence to therapeutic food supplement intake and factors of poor adherence), biochemical measures (CD_4 count, hemoglobin, hematocrit, neutrophil, lymphocytes, platelet), anthropometric measures (Body mass index (BMI)), and life style characteristics (alcohol use, drug use, cigarette use, appetite stimulant use).

Besides this, each participant was interviewed to provide information on adherence to the therapeutic food supplement, factors influencing adherence, life style characteristics, perceived quality of life, and socio-demographic characteristics socio-demographic (age, gender, marital status, education, occupation, monthly income **(**Appendix C). Important items were included in the questionnaires by careful selection to ensure validity. In this process, flow of questions, appropriateness of categorization of variables and presence of sensitive questions were assessed.

The questionnaire included questions covering socio-demographic information, and health related life style characteristics. In addition, the patients' medical records were used to collect information about CD_4 count, hemoglobin, hematocrit, neutrophil, lymphocytes, platelet, the type of therapeutic food supplement and ART drugs prescribed to them.

The explanatory variables were categorized as follows: age (under 20 years, 20-29 years, 30-39 years, 40-49 years, 50-59 years, 60 and older), gender (male/ female), marital status (never in union/ married-living together/widowed, divorced, separated), education (no education/primary/middle & high school/college), occupation (employed/ unemployed), monthly income (<1000 birr/1000-3000bir/>3000birr), date of confirmed HIV+ (continuous variable) ,

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ART medication initiation date (continuous variable), ART drug type (Single/combined(mixed, ≥ 2ART)), therapeutic food supplement intake initiation date (continuous variable), Ready-to-Use Foods (RUFs) type (Plumpy Nut, Plumpy sup, F-75, F-100), adherence to therapeutic food supplement intake (adherence (intake ≥ 95%) /non- adherence (intake <95%)), factors of poor adherence (side effect/share with others/forget /felt better/too ill/ stigma-disclosure/drug stock out/run out of pills, lost/transport, travel problems/alcohol/depression/ other).

Biochemical measures included: CD_4 counts: (stage I: CD4 ≥500cells/µl / stage II: CD4=200-499 cells/µl)/ stage III: CD4<200 cells/µl) , hemoglobin in g/dl, hematocrit in %, anthropometric measures-weight (continuous variable), height (continuous variable), BMI for adults(not malnourished: BMI >18.5/ moderate malnutrition: BMI: 16-18.5 /severe malnutrition: BMI<16).

The six-item short form of US Household Food Security Survey Module and the associated Six-Item Food Security Scale was used to assess food security status. Scores of this survey ranges from 0-6, with lower scores 0-1 indicating food secure; while higher scores 2-4 and 5-6 were indicating low food security and very low food security respectively. During analysis, low food security and very low food security were merged as food insecurity.

Health related lifestyle characteristics measures were- use of alcohol in the past six months (yes/no), use of illegal drugs in the past six months preceding the interview (yes/no), smokes cigarette (yes/no).

The outcome variable in this analysis was measured by asking patients to recall their intake of prescribed therapeutic food supplement in the last seven days prior to the interview. In an attempt to minimize recall bias patients were asked about their adherence over the previous day, previous 3 days and previous week. Self-reported adherence to all therapeutic food supplements will be calculated as the ratio of the doses taken during specific time-period over the total number of therapeutic food supplements doses prescribed to the same time-period. The result were calculated and expressed in percentage and those patients reported intake of 95-100% of the prescribed therapeutic food supplements without delay of more than one hour in the past one week

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were considered adherent to therapeutic food supplement. Similarly, those patients who reported taking less than 95% of the prescribed therapeutic food supplement were considered as non-adherent.

All data collected from the subjects were kept confidential. No name, addresses, or other identifiable information are associated with the data in any way. The data are kept in a locked file cabinet in the principal investigator office. Only the principal investigator and student investigator will have access to this data.

Data Analysis

The data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 24 (IBM SPSS Inc., Chicago, Illinois).

TFSP participants' status and socio-demographic characteristics were compared using chi-square and t-tests (Research Question 1).

The association between food item eaten in the household and food security in HIV infected individuals was investigated using student's t-tests, and chi-square tests (Research Question 2).

The association between therapeutic nutrition supplements intake and nutritional status (as measured by BMI, hemoglobin, hematocrit, neutrophil, lymphocytes, and platelet) in HIV infected adults was investigated using Student's t-tests (Research Question 3).

The association between therapeutic nutrition supplements intake and disease stage (as measured by CD4 and viral load) in HIV infected adults was investigated using student's t-tests, and chi-square tests (Research Question 4).

The association between adherence to therapeutic nutrition supplements intake and factors (reasons) for missing TFS was investigated using chi-square tests (Research Question 5).

The association between therapeutic nutrition supplements intake adherence and health related lifestyle characteristics (as measured by use of alcohol, illegal drugs, smoking cigarette) in HIV infected adults was investigated using chi-square tests (Research Question 6).

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CHAPTER IV. RESULTS

Sample Characteristics

There were 366 participants, 88 (24%) of whom were receiving therapeutic food supplement (TFS). The study aimed at achieving equal numbers in both groups; therapeutic food supplement program (TFSP) participants and Non-TFSP participants. This was not realized because of the prevailing inaccessibility of the TFS by the majority of the patients at the time of data collection. All subjects of the TFSP participants (100%, n=88) were receiving two doses a day of a Ready-to-Use Foods (RUFs) supplement called plumpy nut per day. Each plumpy nut package (dose) weighs 92 g, and provides about 500 kcal (2100 kJ) of energy. According to FMHE (2011), Plumpy Nut contains vitamins A, B-complex, C, D, E, and K, and minerals calcium, phosphorus, potassium, magnesium, zinc, copper, iron, iodine, sodium, and selenium (See APPENDIX-J for detail micronutrient content).

Demographic Characteristics

There were 366 participants included in the analysis. The demographic characteristics of the two groups, therapeutic food supplement program (TFSP) participants and Non-TFSP participants are compared in Table 3. Of the 88 TSFP participants and the 278 Non-TSFP participants, the majority (68.2% and 65.8% respectively) were female. In both the TSFP and the Non-TSFP participants the majority (64.8% and 68.7% respectively) fell within the age range of 30-49 years. Compared with the TSFP group, a higher proportion of the Non-TSFP participants were married (54.7% vs 45.5%).

About 40.9% of the TFSP participants and 27.3% of the Non-TFSP participants had a primary school education, while 35.2% of the TFSP participants and 29.5% of the Non-TFSP participants had a high school education. A smaller proportion of the TFSP participants (3.4%) had college degrees, compared with 10.1% of the Non-TFSP participants. Subjects with no

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education and primary school level of education were significantly more likely to be on the supplement (chi-square statistic=23.806, p=0.000).

Table 3 shows that 76.1% of the TFSP participants had monthly incomes below $1000 birr ($45 USA dollars) compared to 55.4 % the Non-TFSP group. Unemployment was higher in the TFSP group than in the Non-TFSP group (62.5% versus 41.4%). Unemployed subjects, and subjects with monthly incomes below $1000 birr ($45 US Dollars) were significantly more likely to be on the supplement (chi-square statistic=12.001, p=0.000; chi-square statistic=16.967, p=0.000 respectively).

Table 3: Demographic Characteristics by TFSP Participation[1]

Demographic Characteristics	**TFSP (n=88)**	**Non-TFSP (n=278)**	**Total (n=366)**	**Probability Level[2]**
Gender				
Male	28 (31.8)	95 (34.2)	123 (33.6)	0.684
Female	60 (68.2)	183 (65.8)	243 (66.4)	
Age Group (years)				
Under 20	2 (2.3)	5 (1.8)	7 (1.9)	
20-29	6 (6.8)	9 (3.2)	15 (4.1)	
30-39	36 (40.9)	104 (37.4)	140 (38.3)	0.350
40-49	21 (23.9)	87 (31.3)	108 (29.5)	
50-59	15 (17.0)	58 (20.9)	73 (19.9)	
60 and older	8 (9.1)	15 (5.4)	23 (6.3)	
Marital Status				
Never married	11 (12.5)	26 (9.4)	37 (10.1)	
Married	40 (45.5)	152 (54.7)	192 (52.5)	
Widowed	17 (19.3)	58 (20.9)	75 (20.5)	0.302
Separated	8 (9.1)	11 (4.0)	19 (5.2)	
Divorced	11 (12.5)	26 (9.4)	37 (10.1)	
Living Together with a Partner	1 (1.1)	5 (1.8)	6 (1.6)	

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Educational Level				
No Education	14 (15.9)	26 (9.4)	40 (10.9)	
Primary School	36 (40.9)	76 (27.3)	112 (30.6)	
Middle School	3 (3.4)	42 (15.1)	45 (12.3)	0.000
High School	31 (35.2)	82 (29.5)	113 (30.9)	
Some College	1 (1.1)	24 (8.6)	25 (6.8)	
College Degree	3 (3.4)	28 (10.1)	31 (8.5)	
Monthly Income Category				
<1000 Birr ($45 US Dollars)	67 (76.1)	154 (55.4)	221 (60.4)	
1000-3000 Birr ($45-135 US Dollars)	20 (22.7)	82 (29.5)	102 (27.9)	0.000
>3000 Birr (Over $135 US Dollars)	1 (1.1)	42 (15.1)	43 (11.7)	
Employment Status				
Unemployed	55 (62.5)	115 (41.4)	170 (46.4)	0.000
Employed	33 (37.5)	163 (58.6)	196 (53.6)	

[1]All variables reported as n (%)
[1]Probability levels below 0.05 indicate significant relationship of demographic characteristic to TSFP participation

BMI, Hemoglobin, and Hematocrit

Table 4 shows the mean values for BMI, hemoglobin, and hematocrit by TFSP participation. Mean BMI values in Non-TFSP participants were significantly higher at baseline, six months and twelve months. Mean hemoglobin and hematocrit values were significantly higher in the Non-TFSP than in the TFSP participants at baseline and six months. There were no significant differences between the two groups in mean values of hemoglobin and hematocrit at twelve months.

Table 4: BMI, Hemoglobin, and Hematocrit by TFSP Participation

	TFSP Mean ± SEM	**Non-TFSP Mean ± SEM**	**Probability Level[1]**
BMI (kg/m^2)	(n=88)	(n=278)	
Baseline	17.4± 0.2	22.3 ± 0.2	0.000
Six Months	17.7 ± 0.2	22.5 ± 0.2	0.000
Twelve Months	17.8 ± 0.2	22.7 ± 0.2	0.000

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Hemoglobin (g/dL)			
Baseline	13.2 ± 0.3 (n=57)	14.5 ± 0.1 (n=205)	0.000
Six Months	13.3 ± 0.3 (n=22)	14.8 ± 0.2 (n=137)	0.001
Twelve Months	14.1 ± 0.3 (n=42)	14.5 ± 0.1 (n=92)	0.278
Hematocrit (%)			
Baseline	39.7 ± 1.1 (n=46)	43.1 ± 0.5 (n=175)	0.002
Six Months	40.1 ± 1.0 (n=15)	43.9 ± 0.5 (n=107)	0.005
Twelve Months	43.6 ± 1.1 (n=32)	42.5 ± 0.5 (n=77)	0.242

[1]Probability levels below 0.05 indicate significant differences in the means of the two groups

Table 5 shows comparisons of the mean values for BMI, hemoglobin, and hematocrit measures at baseline, six months, and twelve months within the TFSP group. There was a significant increase in BMI at twelve months compared to the baseline. There were also significant increases in hemoglobin from baseline to six and twelve months, and from six months to twelve months. The small sample sizes for the hemoglobin and hematocrit pairs should be noted.

Table 5: Comparison of BMI, Hemoglobin, and Hematocrit Measures within the TFSP Group

	Mean ± SEM	**n**	**Probability Level[1]**
BMI Baseline (kg/m^2) BMI Six Months (kg/m^2)	17.4 ± 0.2 17.8 ± 0.2	88 88	0.073
BMI Baseline (kg/m^2) BMI Twelve Months (kg/m^2)	17.4 ± 0.2 17.8 ± 0.2	88 88	0.039
BMI Six Months (kg/m^2) BMI Twelve Months (kg/m^2)	17.7 ± 0.2 17.8 ± 0.2	88 88	0.219
Hemoglobin Baseline (g/dL) Hemoglobin Six Months (g/dL)	12.5 ± 0.4 13.6 ± 0.3	16 16	0.013

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Hemoglobin Baseline (g/dL) Hemoglobin Twelve Months (g/dL)	13.0 ± 0.4 14.5 ± 0.4	25 25	0.001
Hemoglobin Six Months (g/dL) Hemoglobin Twelve Months (g/dL)	13.5 ± 0.3 14.0 ± 0.3	18 18	0.017
Hematocrit Baseline (%) Hematocrit Six Months (%)	35.0 ± 3.4 41.0 ± 1.3	8 8	0.071
Hematocrit Baseline (%) Hematocrit Twelve Months (%)	38.9 ± 1.9 44.7 ± 1.7	16 16	0.016
Hematocrit Six Months (%) Hematocrit Twelve Months (%)	40.0 ± 1.3 41.9 ± 1.6	10 10	0.106

[1]Probability levels below 0.05 indicate significant differences

Based on the Ethiopian Guide to Clinical Nutrition Care for Children and Adults Living with HIV (FMHE 2011), the BMI status of the TFSP and Non-TFSP participants were categorized based on the three classifications of nutritional status for adults: severe malnutrition (BMI<16 kg/m^2, moderate malnutrition (BMI 16-18.5 kg/m^2), and not malnourished (BMI>18.5 kg/m^2). At baseline, six-months, and twelve months, the majority of the TFSP participants were moderately malnourished (68.2%, 63.6%, and 61.4% respectively), while the majority of the Non-TFSP participants were not malnourished (79.9%, 83.8%, and 84.5% respectively). Also, the percentage of severe malnutrition status (BMI<16.0 kg/m^2) within the TFSP participants declined from baseline (19.3%), to six months (8.0%) and twelve months (10.2%) (Table 6).

Table 6: BMI Status by TFSP Participation[1]

BMI Status	**TFSP (n=88)**	**Non-TFSP (n=278)**	**Total (n=366)**
Baseline BMI (kg/m^2)			
Severe malnutrition (BMI<16)	17 (19.3)	12 (4.3)	29 (7.9)
Moderate malnutrition (BMI 16-18.5)	60 (68.2)	44 (15.8)	104 (28.4)
Not malnourished (BMI>18.5)	11 (12.5)	222 (79.9)	233 (63.7)
Six-month BMI (kg/m^2)			

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Severe malnutrition (BMI<16)	7 (8.0)	4 (1.4)	11 (3.0)
Moderate malnutrition (BMI 16-18.5)	56 (63.6)	41 (14.7)	97 (26.5)
Not malnourished (BMI>18.5)	25 (28.4)	233 (83.8)	258 (70.5)
Twelve-month BMI (kg/m^2)			
Severe malnutrition (BMI<16)	9 (10.2)	8 (2.9)	17 (4.6)
Moderate malnutrition (BMI 16-18.5)	54 (61.4)	35 (12.6)	89 (24.3)
Not malnourished (BMI>18.5)	25 (28.4)	235 (84.5)	260 (71.0)

[1]All variables reported as n (%)

At baseline, six-months, and twelve months, the TFSP participants were more likely to be severely or moderately malnourished (Table 7).

Table 7: Relationships of BMI Status to TFSP Participation

	Chi-square Statistic	Probability Level[1]
Baseline BMI kg/m^2	131.096	0.000
Six-month BMI kg/m^2	98.827	0.000
Twelve-month BMI kg/m^2	102.8	0.000

[1]Probability levels below 0.05 indicate significant relationships of BMI status to TFSP participation

Food Security

Table 8 shows the food security levels of the participants by TFSP participation. The six-item short form of US Household Food Security Survey Module and the associated Six-Item Food Security Scale were used in determining the food security levels (USDA, 2012). In both the TFSP and Non-TFSP groups the majority of the subjects had low or very low food security levels (88.6% and 69.1% respectively), the levels of low and very low food security levels being higher in the TFSP participants.

A significant relationship was found between food security and TFSP participation (chi-square statistic=13.232, p=0.000). TFSP participants were more likely to be food insecure.

Table 8: Food Security Levels by TFSP Participation[1]

Food Security Levels	**TFSP (n=88)**	**Non-TFSP (n=278)**	**Total (n=366)**
High/Marginal Food Security (score 0-1)	10 (11.4)	86 (30.9)	96 (26.2)

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Low Food Security (score 2-4)	43 (48.9)	110 (39.6)	153 (41.8)
Very Low Food Security (score 5-6)	35 (39.8)	82 (29.5)	117 (32.0)

[1]All variables reported as n (%)

Disease Stage

Table 9 shows the mean and standard error of measured immunological parameters (CD4 cells count, lymphocyte count, neutrophil count, and platelet count) at baseline, six months, and twelve months. No significant differences were found.

Table 9: Disease Stage Measures by TFSP Participation

Disease Stage Measures	**TFSP Mean ± SEM**	**Non-TFSP Mean ± SEM**	**Probability Level[1]**
CD4 Cell Count (cells/µl)			
Baseline	400.0 ± 40.7 (n=62)	423.6 ± 17.9 (n=218)	0.278
Six-month	621.3 ± 81.3 (n=23)	525.8 ± 18.9 (n=158)	0.132
Twelve-month	502.6 ± 36.0 (n=45)	549.0 ± 23.6 (n=132)	0.155
Lymphocyte Count (%)			
Baseline	33.1 ± 2.4 (n=22)	36.8 ± 1.0 (n=135)	0.082
Six-month	37.0 ± 5.9 (n=8)	33.3 ± 1.1 (n=65)	0.277
Twelve-month	40.0 ± 2.6 (n=17)	35.7 ± 1.6 (n=57)	0.104
Neutrophil Count (%)			
Baseline	56.5 ± 2.8 (n=20)	52.4 ± 1.2 (n=124)	0.097
Six-month	52.0 ± 8.1 (n=6)	55.5 ± 1.6 (n=56)	0.248
Twelve-month	49.5 ± 3.2 (n=15)	52.5 ± 1.8 (n=54)	0.219
Platelets Count ($x10^3$/L)			
Baseline	288.2 ± 22.7 (n=23)	278.9 ± 7.7 (n=133)	0.328
Six-month	246.0 ± 47.7 (n=6)	282.0 ± 10.4 (n=64)	0.166
Twelve-month	300.9 ± 26.5 (n=16)	326.0 ± 12.9 (n=53)	0.184

[1]No significant differences found

Table 10 shows comparisons of the mean disease stage measures with the TFSP group. There were significant increases in the mean CD4 cell counts from baseline to six months, and

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from baseline to twelve months. No significant differences were found in lymphocyte, neutrophil, and platelet cell counts mean from baseline to six and twelve months, and from six months to twelve months. Sample sizes were small for the disease stage measures pairs.

Table 10: Comparison of Disease Stage Measures within the TFSP Group

	Mean ± SEM	**N**	**Probability Level[1]**
CD4 Cell Count Baseline (cells/µl) CD4 Cell Count Six Months (cells/µl)	309.8 ± 55.2 647.9 ± 103.4	17 17	0.001
CD4 Cell Count Baseline (cells/µl) CD4 Cell Count Twelve Months (cells/µl)	309.8 ± 57.2 510.0 ± 51.0	29 29	0.015
CD4 Cell Count Six Months (cells/µl) CD4 Cell Count Twelve Months (cells/µl)	735.5 ± 148.3 547.9 ± 77.4	11 11	0.059
Lymphocyte Count Baseline (%) Lymphocyte Count Six Months (%)	29.3 ± 6.9 20.5 ± 8.3	3 3	0.273
Lymphocyte Count Baseline (%) Lymphocyte Count Twelve Months (%)	40.8 ± 5.9 45.1 ± 7.1	5 5	0.275
Lymphocyte Count Six Months (%) Lymphocyte Count Twelve Months (%)	37.1 ± 5.3 33.2 ± 0.8	3 3	0.198
Neutrophil Count Baseline (%) Neutrophil Count Six Months (%)	61.3 ± 4.5 71.7 ± 9.0	3 3	0.223
Neutrophil Count Baseline (%) Neutrophil Count Twelve Months (%)	47.9 ± 7.5 46.1 ± 10.1	4 4	0.314
Neutrophil Count Six Months (%) Neutrophil Count Twelve Months (%)	56.3 ± 3.6 59.7 ± 0.9	3 3	0.232
Platelets Count Baseline (%) Platelates Count Six Months (%)	370.7 ± 42.8 197.3 ± 81.2	3 3	0.147
Platelets Count Baseline (%) Platelets Count Twelve Months (%)	264.0 ± 17.9 279.5 ± 33.5	4 4	0.329

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Platelets Count Six Months (%) Platelets Count Twelve Months (%)	291.3 ± 46.4 404.0 ± 40.6	3 3	0.071

[1]Probability levels below 0.05 indicate significant differences

Based on Nelms et al. (2016), the CD4 cell counts of the TFSP and Non-TFSP participants were categorized based on the three classifications of disease stage for adults: Stage I: CD4≥500 ; Stage II: CD4=200-499; and Stage III: CD4<200 (see Table 11). Only 25.8% of the TFSP participants and 33.9% of the Non-TFSP participants had CD4 cell counts of 500 cells/µl or more at baseline, while at six months, the majority of TFSP participants (52.2%) had CD4 cell counts of 500 cells/µl or more. At twelve months the majority of both TFSP and Non-TFSP participants had CD4 cell counts of 500 cells/µl or more.

Table 11: CD4 Cell Count Stage by TFSP Participation[1]

CD4 Cell Count Stage (cells/µl)	**TFSP(n=62)**	**Non-TFSP (n=218)**	**Total (n=280)**
Baseline			
Stage I: CD4≥500	16 (25.8)	74 (33.9)	90 (32.10)
Stage II: CD4=200-499	27 (43.5)	99 (45.4)	126 (45.0)
Stage III: CD4<200	19 (30.6)	45 (20.6)	64 (22.9)
	TFSP (n=23)	**Non-TFSP (n=158)**	**Total (n=181)**
Six Months			
Stage I: CD4≥ 500	12 (52.2)	76 (48.1)	88 (48.6)
Stage II: CD4=200-499	8 (34.8)	68 (43.0)	76 (42.0)
Stage III: CD4<200	3 (13.0)	14 (8.9)	17 (9.4)
	TFSP (n=45)	**Non-TFSP (n=132)**	**Total (n=177)**
Twelve Months			
Stage I: CD4≥500	24 (53.3)	71 (53.8)	95 (53.7)
Stage II: CD4=200-499	16 (35.6)	51 (38.6)	67 (37.9)
Stage III: CD4<200	5 (11.1)	10 (7.6)	15 (8.5)

[1]All variables reported as n (%)

Table 12 shows that no significant relationships of CD4 cell count stage to TFSP participation were found at baseline, six months, or twelve months.

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Table 12: Relationships of CD4 Cell Count Stage to TFSP Participation

CD4 Cell Count Stage	Chi-square Statistic	Probability Level[1]
Baseline	3.145	0.208
Six Months	0.768	0.681
Twelve Months	0.580	0.748

[1]No significant relationships found

As shown in Table 13, the ART initiation period for only 2.7% of the subjects was less than 24 months. The majority (97.3%) of the subjects were under ART treatment for 24 months or more.

Table 13: ART Initiation Period

Variable	Number	Percent
ART initiation (months)		
< 24	10	2.7
≥ 24	356	97.3
Total	366	100.00

Table 14 provides an overview of the ART regimens. At the time of the study, all patients were receiving free ART. Most of the participants (93.7%) were taking the first line standard ART regimens consisting of a combination of nucleoside reverse transcriptase inhibitors (NRTIs), and non-nucleoside reverse transcriptase inhibitors (NNRTIs). TDF-3TC-EFV and TDF+3TC+NVP were the two major combinations of ART taken by 35.0% (128) and 33.6 % (123) of the subjects respectively. Only 6.3 % (n=23) of the subjects were at second line therapy.

Table 14: Distribution of the Participants According to ART Regimens[1]

Participants Current ART Regimens	TFSP (n=88)	Non- TFSP (n=278)	Total (n=366)
Adult First Line ART Regimens			
1c = (AZT-3TC-NVP)	10 (11.4)	25 (9.0)	35 (9.5)
1d = (AZT-3TC-EFV)	6 (6.8)	47 (16.9)	53 (14.5)
1e = (TDF-3TC-EFV)	45 (51.1)	83 (29.9)	128 **(35.0)**

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1f = (TDF+3TC+NVP)	18 (20.5)	105 (37.8)	123 **(33.6)**
1g = (ABC+3TC+EFV)	1 (1.1)	3 (1.1)	4 (1.1)
First line ART regimens Total	80 (90.9)	263 (94.7)	343 **(93.7)**
Adult Second Line ART Regimens			
2g = (TDF-3TC-LPV/r)	5 (5.7)	6 (2.2)	11 (3.0)
2h =(TDF-3TC-ATV/r)	3 (3.4)	7 (2.4)	10 (2.7)
2i = (ABC+3TC+LPV/r)	0	2 (0.7)	2 (5)
Second line ART regimens Total	8 (9.1)	15 (5.3)	23 **(6.3)**

[1]All variables reported as n (%); AZT: Azidothymidine, also known as Zidovudine; 3TC: Lamivudine; NVP: Nevirapine; EFV: Efavirenz; TDF: Tenofovir Disoproxil Fumatrate; ABC: Abacavir; ATV/r: Atazanavir/ Ritonavir; LPV/r: Lopinavir/Ritonavir boosted

Therapeutic Food Supplement Consumption and its Barriers

Of the 88 TFSP participants, the majority 78.4 % (69) did not miss taking the therapeutic food supplement. Patients who reported missing TFS intake doses in the last seven days (n=19) were further asked to indicate the principal barriers to treatment adherence. The most frequently cited reasons for missing TFS intake according to the prescribed schedule in descending order of magnitude were as follows: too ill (31.6%), forgot (26.3%), felt better (21.0%), drug store out of stock (15.8%), and Lack of transport towards clinic (5.3%) (see Table15).

Table 15: Reasons for Missing TFS Intake

Variable	Number	Percent
Too ill	6	31.6
Forgot	5	26.3
Felt better	4	21.0
Drug store out of stock	3	15.8
Lack of transport towards clinic	1	5.3
Total	19	100

Lifestyle Characteristics Related to TFSP Adherence[1]

Table 16 presents health-related lifestyle characteristics by TFS intake adherence status. In this study, small proportions of the adherents of TFS intake consumed alcoholic beverages (4.3%), used illegal drugs (5.8%), or consumed appetite stimulants (10.1%). Similarly, small proportions of the non-adherents of TFS intake used illegal drugs (10.5%), or consumed appetite

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stimulants (10.1%), and none consumed alcoholic beverages. None of the TFS participants smoked cigarettes.

Table 16: Health-related Lifestyle Characteristics by TFS Adherent Status

Therapeutic Food Supplement Intake Adherence Status		
Variable	**Adherent (n=69)**	**Non-Adherent (n=19)**
Consumption of Alcoholic Beverages		
Yes	3 (4.3)	0 (0.0)
No	66 (95.7)	19 (100.0)
Illegal Drug Use		
Yes	4 (5.8)	2 (10.5)
No	65 (94.2)	17 (89.5)
Smoked Cigarettes		
Yes	0 (0.0)	0 (0.0)
No	69 (100.0)	19 (100.0)
Consumption of Appetite Stimulants		
Yes	7 (10.1)	4 (21.1)
No	62 (89.9)	15 (78.9)

[1]All variables reported as n (%)

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CHAPTER V. DISCUSSION

In this study only 24% of the subjects had access to the therapeutic food supplement program (TFSP). In Ethiopia TFSP is an entitlement program available to all who meet eligibility requirements of BMI less than 18.5 kg/m^2. For HIV positive clients, eligibility requirements to participate in a TFSP are BMI<18.5 kg/m^2, or having unintentionally lost 5-10% of their weight within 2 months of ART assessment (FDREMH, 2008).

With regard to gender, females accounted for the higher proportion of people on ART (66.4%) compared to the males (33.6%). This finding is in accordance with the report by FHAPCO (2014) which indicates the prevalence of HIV being higher among females than males (also see Appendix H). According to UNAIDS (2013), evidence has shown that females bear the larger burden of HIV in sub-Saharan Africa. Another possible reason for the smaller percentage of males in the study is that men may be reluctant to go to a voluntary HIV counselling and testing center to determine their HIV status, whereas during antenatal care most females go to voluntary HIV counselling and testing centers to ascertain their status.

Fields-Gardner and Campa (2010) stated that more than two-thirds of people living with HIV in the United States were between 25 and 49 years of age. The majority of the participants of this study were between 20 and 49 years. As shown in Table 3, the age groups 30-39 years, and 40-49 years comprised 38.0% and 29.5% of the sample respectively. This indicates that most of the study participants were young adults.

The majority of the subjects (52.5%) were married, with the remaining being widowed (20.5%), divorced (10.1%), never married (10.1%), separated (5.2%), and living together with a partner (1.6%). The results presented in Table 3 indicated that 84.7% of the study population (95.6% of TFSP participants) had 12 grader or lower levels of education. Also, 76.1% of the subjects had monthly incomes below 1000 Ethiopian birr ($45 US Dollars/month), and 62.5

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percent were unemployed. Education level has a direct relationship with monthly income and unemployment status in the society. The demographic characteristics of our study population are similar to recent studies in HIV infected adults which were conducted in different geographic locations in Ethiopia. Married marital status, educational level up to 12 grade, monthly incomes less than 1000 ETB, and unemployment status were reported in a study conducted in North Ethiopia (the prevalences being 41.1%, 88.2%, 76.1%, and 20.1% respectively) (Berhe et al. 2013), while in Butajira, Ethiopia the distribution of the same parameters was 51.1%, 93.1%, 86.7%, and 22.0 % respectively (Gede et al., 2015). In a study conducted in Jimma, Ethiopia, 48.6% of people living with HIV (PLHIV) were married, 84.6% had monthly incomes less than 1000 ETB, and 23.5% were unemployed (Tiyo et al., 2012).

These results also showed that subjects with no education and primary school level of education were significantly more likely to be on the supplement. Also, unemployed subjects and subjects with monthly incomes below $1000 birr (<$45 US dollars) significantly more likely to be on the supplement.

According to the WHO (2009), the nutritional requirements of people living with HIV are influenced by several factors, including age, physiological changes (pregnant, breastfeeding), physical activity, progress of the infection, metabolism and viral load count. The World Health Organization (WHO) recommends that PLHIV increase energy intake incrementally depending on the stage of the disease (WHO, 2009). It is reported that in HIV-infected *asymptomatic* and HIV-infected symptomatic people, energy intake should increase by 10% and 20-30% respectively over the level of energy intake recommended for healthy, non-HIV-infected people of the same age, gender, and physical activity level (Louay Labban, 2016; TFNC, 2016; HAPCO and GAMET, 2008).

According to the WHO (2009)**,** nutritional care and support enables people living with HIV/AIDS to obtain the energy and nutrients to meet their nutritional needs, maintain optimal nutritional status, manage symptoms, support immune function, and prevent weight loss. Ndekha

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(2009) reported that patients who had already lost a significant amount of weight and were given supplements containing amino acids, antioxidant vitamins, minerals, and counseling gained weight, and experienced increases in muscle mass. Koethe et al. (2009) reported that in the management of HIV/AIDS, nutrition intervention programs have markedly improved both the patients' body weights and general health.

The Ethiopian health system has been implementing a Food by Prescription (FBP) program since 2010. FBP is a facility-based therapeutic and supplementary feeding intervention which has targeted and enabled malnourished HIV infected individuals to fulfill the indications for nutrition therapy (Tufts University; USAID, 2012). Manary and Sandige (2006) report that the majority of therapeutic foods have been designed as treatment for acute to severe malnutrition.

Ready-to-Use Therapeutic Food (RUTF) is one of the products in use for management of adult wasting, especially in PLHIV, and is effective in improving body mass index (BMI), CD4 cell count, health and functional status (Bowie et al., 2005; Diop et al., 2003; Ndekha et al., 2009a). According to the Federal Democratic Republic of Ethiopia Ministry of Health National Guidelines for HIV/AIDS and Nutrition (FDREMH, 2008), a BMI less than 18.5 kg/m^2 is the eligibility criterion to place HIV/AIDS patients on the therapeutic food supplement support program as part of clinical HIV care treatment. In the current study there were 366 participants, 88 (24%) of whom were receiving a Ready to Use Therapeutic Food, Plumpy'Nut. Plumpy'Nut is packaged in foil sachets weighing 92 grams, each containing 500 kilocalories (2100 kJ).

The subjects' nutritional status measure (BMI), hemoglobin, and hematocrit were presented in Table 4. When compared with the TFSP participants, mean BMI values in Non-TFSP participants were significantly higher at baseline, six months and twelve months. However, within the TFSP group a significant increase in BMI occurred within the TFSP group from baseline to twelve months (see Table 5). Also, there were significant increases in hemoglobin from baseline to six months, and from six months to twelve months (though sample

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sizes were small) (see Table 5). Hematocrit increased significantly from baseline to six and twelve months, and from six months to twelve months. In our finding, at baseline only a small proportion of the TFSP participants (12.5%) were not malnourished (BMI>18.5 kg/m^2) compared to 79.9% of the Non-TFSP participants group (Table 6). At 12 months of treatment the prevalence of severe malnutrition (BMI<16 kg/m^2) for the TFSP participants had dropped from 19.3% to 10.2%. Conversely, the percentages of TFSP participants who were not malnourished (BMI>18.5 kg/m^2) had improved from 12.5% at baseline to 28.4% at 12 months of treatments. At baseline, six-months, and twelve months, the majority of the TFSP participants were moderately malnourished (68.2%, 63.6%, and 61.4% respectively), while the majority of the Non-TFSP participants were not malnourished (79.9%, 83.8%, and 84.5% respectively). These results also showed that TFSP participants were more likely to be severely or moderately malnourished (Tables 6 and 7). These results are in disagreement with those of Ndekha et al. (2009), Ahoua et al. (2009), Oosterhout and Ndekha (2009), and Sunguya et al. (2012) where the majority of the HIV positive individuals treated with ready-to-use food supplement (RUFS) showed increases in BMI (UNICEF, 2013).

Ndekha et al. (2009a) conducted a randomized controlled trial in Malawi to investigate the effects of RUFS in achieving weight gain and an increase in BMI in HIV adults after 3½ months of treatment. Subjects were 491 HIV positive adults who were under ART treatment. All participants had a BMI of less than 18.5 kg/m^2. After 3½ months, participants in the RUFS group reported a 5.6 kg weight gain, and BMI increased by 2.2 Kg/m^2. Similarly, a weight gain of 4 kg, and an increase in BMI of 1.7 kg/m^2 were reported in a study conducted in Kenya and Uganda by Ahoua et al. (2009). Also, Oosterhout and Ndekha, 2009 reported weight gain of 6.9 kg, and an increase in BMI of 2.7 kg/m^2 following RUFS supplementation in Malawi.

Sunguya et al. (2012) found that supplementation with RUTF for at least four months had the potential to improve undernutrition among HIV-positive children in ART clinical settings. In a study conducted in central Haiti, providing food assistance to HIV-infected led to improved

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BMI, food security and adherence to clinical visits (Ivers et al., 2010). The results of the current study are not in line with these studies which reported weight gain, and an increase in BMI due to the subjects' consumption of RUFS. The possible explanation for this difference might be differences in the following: (1) study design, (2) study duration, (3) sample size, (4) BMI cut off value to be eligible for the therapeutic food supplement program, and (5) the socio-economic status of the study population, household food security status, and the HIV disease stages. For instance Ahoua et al. (2009) conducted a retrospective cohort analysis of patients aged 15 years or older with a BMI of less than 17 kg/m2 for 30 months between March 2006 and August 2008. Overall, 1340 HIV-positive adults were enrolled and participated in a ready-to-use therapeutic food program. The findings of Ahoua et al. (2009) suggest that nutrition therapy administration in conjunction with an early start of ART might increase the chances of nutritional recovery in severely malnourished HIV patients. On the other hand Ndekha et al. (2009) conducted a randomized, investigator blinded, controlled trial on patients aged 18 years or older with a BMI of less than 18.5 kg/m2 for 3.5 months, and investigated the effects of two different food supplements on BMI in wasted Malawian adults with HIV. The sample size was 491. The findings of Ndekha et al. (2009) indicated a greater increase in BMI and lean body mass due to supplementary feeding with a fortified spread and corn-soy blend.

This study documented the high prevalence of household food insecurity, and the association between food insecurity and TFSP participation status among HIV-positive patients. According to Coleman-Jensen (2010), food insecurity is defined as "limited or uncertain availability of nutritionally adequate and safe foods or limited or uncertain ability to acquire acceptable foods in socially acceptable ways". Alston et al. (2009) reported that poor households often suffer from food insecurity. International studies suggest that food insecurity may affect the health of the HIV-infected in a number of ways (Anema et al., (2009); Weiser et al., (2009); Cantrell et al., (2008);Bukusuba et al., (2007). For example, there is some evidence that food insecurity among HIV-infected participants receiving antiretroviral medications is associated

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with unsuppressed viral load and may render treatment less effective (Wang et al., 2011; Weiser et al. 2011). In similar studies in the Boston and Providence areas, food insecurity was longitudinally associated with lower CD4 counts among HIV-positive adults (McMahon et al.' 2011). In Atlanta food insecure HIV-positive adults had lower CD4 counts and higher viral loads compared to their food secure peers (Kalichman et al., 2010).

According to the Food and Agriculture Organization (FAO, 2014), the number of chronically undernourished people in the world stood at 805 million between 2012 and 2014. When addressing food insecurity crises of the world, FAO (2010) reports that 41% of the Ethiopian population lives below the poverty line and more than 38 million people are undernourished. In this study, more than three-fourths (88.7%) of the TFSP participants experienced food insecurity. This rate is higher than the Non-TFSP participants' food insecurity rate of 69.1% (Table 8). These findings could be due to the more food insecure status of the TFSP participants who were probably demanding more supplemental nutrition support than the Non-TFSP participants. Another explanation is that those who did not receive TFSP may have potentially better ability to purchase foods items so that they are requiring less or no TFSP support. This is supported by the finding that 10.1% of the Non-TFSP participants had college degrees compared to 3.4% of the TFSP participants group (see Table 3). Further, unemployment was higher in the TFSP group than the Non-TFSP group (62.5% versus 41.4%). Over 15% of the Non-TFSP participants had monthly incomes greater than $3000 birr compared to 1.1% the TFSP group (Table 3).

High food insecurity rates have consistently been reported among persons living with HIV in Ethiopia. In this study, the overall prevalence of food insecurity was 73.8% (sum total of low food security 41.8%, and very low food security 32.0%). This finding was relatively higher than previous reports conducted in the Jimma zone of Southwest Ethiopia (63.0%) (Tiyou et al., 2012), Western Kenya (33.5%) (Mamlin et al., 2009). However, the results of the current study were relatively similar to a previous report conducted at the Butajira Hospital, Southern Ethiopia

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(78.1%) (Gedle et al., 2015), and in Dire-Dawa, Southwest Ethiopia (72.4%) (Amberbir et al., (2008). The inconsistency of food insecurity among the study population is might be due to the variation in their geographic locations, socio-economic status, and their cultural and ethnic experiences.

Disease Stage

According to Shalini et al. (2012), both malnutrition and HIV reduces CD4 counts, thereby reducing the immunity of the patient. The HIV and AIDS effects on nutrition include reduced food intake, poor absorption of nutrients and changes in metabolism (Dolan et al., 2007). In this study more than half, 53.3% and 53.8% (TFSP and Non-TFSP participants respectively) of the subjects experienced CD4 cell count greater or equal to 500 cells per microliter at the end (at twelve months) of the study period (Table 11). This rate is higher than the CD4 rate (CD4≥500 cells/µl) of the Southern Ethiopia, Butajira Hospital rate of 34.6% reported in 2015 (Gedle et al., 2015).

In this study significant differences between TFSP participants and Non-TFSP participants in and CD4 cells count at baseline, six months, and twelve months were not found (Table 9). Within the TFSP group there were significant increases in the mean CD4 cell counts from baseline to six and twelve months (Table 10). Fawzi et al. (2004), and Kaiser et al. (2006) found increases in CD4 cell count in HIV-infected patients receiving micronutrients supplements, including selenium, N-acetyl cysteine and L-glutamine. Table 12 shows that there were no significant relationships of CD4 cell count to TFSP participation s during the study periods.

In this study, the majority of TFSP participants (51.1%) were taking the First Line ART Regimens1e (TDF-3TC-EFV). Similarly, in a previous report from Butajira Hospital, Southern Ethiopia, the majority of patients (42%) were on ART regimen 1e (Gedle et al., 2015).

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Therapeutic Food Supplement Consumption and its Barriers

According to the WHO (2017), adherence, in the context of treatment, is defined as the extent to which a patient's behavior (taking medication, following a diet, modifying habits, or attending clinics) coincides with medical or health advice. It is considered a primary determinant of the effectiveness of treatment (Aakhus et al. 2014; Jimmy, B., & Jose, J. 2011; KMOH, 2004). Of the 88 TFSP participants of the current study, 11.6% (n=19) reported missing TFS intake doses in the last seven days (Table 15). Previous research suggests that non-adherence to treatment may affect health in a number of ways (Aakhus et al., 2014; Jimmy, B., & Jose, J. 2011; KMOH, 2004). For example, there is some evidence that HIV-infected people who do not adhere to their treatment experience inadequate suppression of viral replication, continued destruction of CD4 cells, progressive decline in immune function and disease progression compared with individuals who are adherent to treatment (Aakhus et al., 2014; Jimmy, B., & Jose, J. 2011; KMOH, 2004).

In this study, the three main reasons accounted for missing TFS intake were being too ill (31.6%), simply forgetting to take the TFS (26.3%), and (3) feeling better (21.0%) (Table15). This finding correlates with the finding of other studies on adherence to antiretroviral therapy. At the Yirgalem Hospital, South Ethopia the main reason for non-adherence cited by patients were patients simply forgetting (51%) (Markos et al., 2008), compared with 38% in Nairobi, Kenya (Wakibi et al., 2011). The possible explanation for the lower rate in this study might be due to using a one week adherence assessment, and using self-reports. As far as can be determined, this is the first study to assess factors associated with adherence to TFS intake among HIV patients at St. Paul's Hospital, Addis Ababa, Ethiopia, and the first to examine adherence among patients who are receiving free TFS services at government hospitals.

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Lifestyle Characteristics Related to TFSP Adherence

According to Boodram et al. (2009), life style characteristics such as smoking, and alcohol use are the most robust predictor of lower BMI among HIV+ individuals. The differences observed between being adherent or non-adherent to TFSP participation with respect to illegal drug use with those non-adherent to TFSP using more illegal drug, may be related to having more income to spend on non-nutritive items.

Table 16 presents health-related lifestyle characteristics by TFS intake adherence status. One hundred percent of both the adherents and non-adherents did not consume alcoholic beverage and cigarettes. Therefore, alcoholic beverage consumption and use of cigarettes are not consider predictors of non-adherence in this study. However, several other studies have shown that adherence decreases with increases in alcohol use, illegal drug use, and smoking cigarettes (Thames et al., 2012; Ortego et al., 2011; Wasti et al., 2011; Arnsten and Li, 2007).

Data from Table 16 showed that the percentage of illegal drug consumption by the non-adherents of TFS intake was higher than in the adherent group (10.5% vs 5.8% respectively). According to Lucas (2011), Ortego et al. (2011), and Chesney (2006) patients with histories of substance use are more likely to exhibit higher rates of refusal of treatment, and are significantly less engaged with their health care providers.

Discussion of the Hypotheses

Hypothesis 1: It was hypothesized that the subjects who were TFSP participants would be more likely to be female, younger, married, less educated, unemployed, and have lower monthly incomes.

This hypothesis was supported. Table 3 shows that the majority of TFSP participants are female (68.2%); younger adults of age between 30-49 years (74.8%), married (45%), less

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educated/less or received a high school diploma (95.6%), unemployed (62.5%), and have lower monthly incomes (income less than $1000 ETB; 76.1%).

There were no significant differences between the two groups in terms of gender, age group, and marital status. However, subjects with no education and primary school level of education, unemployed subjects, and subjects with monthly incomes below $1000 birr (<$45 US dollars) were significantly more likely to be on the supplement.

Hypothesis 2: It was hypothesized that there is a significant, positive association between therapeutic food supplement intake and nutritional status improvement.

This hypothesis was not supported. According to the results of this study statistically there were no significant differences found in the improvement of body mass index (BMI), hemoglobin, and hematocrit level between TFSP and Non-TFSP participants. However, Table 4 shows that subjects who received TFS had lower levels of BMI, hemoglobin, and hematocrit compared to the Non-TFSP participants. In addition to this, Table 6 shows that the percentage of severe malnutrition within the TFSP participants dropped from baseline, to six months, and twelve months.

Hypothesis 3: It was hypothesized that there is a significant, positive association between therapeutic food supplement intake and food security.

The hypothesis was not supported. Table 8 shows that TFSP participants were more likely to not be food secure. Although the results in this study did not reveal a significant relationship between TFS intake and food security, there is a research that validates the importance of studying the correlation. Research has found that PLHIVs that do not have sufficient food intake due to food insecurity should be provided food supplements to help cover their deficits (Gardner, 2007).

Hypothesis 4: It was hypothesized that the therapeutic food supplement receiving group will have significantly less advanced disease stage than the non-receiving groups.

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Table 12 shows that there were no significant differences in disease stage measures (CD4 cell count, lymphocyte count, neutrophil count, and platelet count) between TFS receiving and non-receiving groups during the study periods.

Hypothesis 5: It was hypothesized that TFSP participants who are consumer of alcoholic beverages, illegal drugs, and cigarette are more likely to be non-adherents to TFS intake.

The analysis of TFSP participation and health-related lifestyle characteristics (consumption of alcoholic beverages, use of illegal drugs, and smoking cigarettes) could not be tested statistically because of the small numbers of subjects who reported these practices.

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CHAPTER VI. CONCLUSIONS AND RECOMMENDATIONS

Conclusions

The focus of this study was to investigate the impacts of taking therapeutic food supplements on nutritional status, food security, disease stage and health related lifestyle characteristics of people living with HIV and AIDS who are under ART. This study was characterized by a convenience sample of 366 HIV infected adults, who were participants and non-participants of the TFSP in St. Paul's Hospital, Addis Ababa, Ethiopia.

In the current study, the TFSP participation rate was 24%. The findings indicated that the TFSP participation rates among females and males were 66.4% and 33.6% respectively. Also, in both the TSFP and the Non-TSFP participants the majority (64.8% and 68.7% respectively) fell within the age range of 30-49 years. A higher proportion of both the TSFP participants and the Non-TSFP participants were married (54.7% vs 45.5% respectively), had high school diploma or lower education levels (95.4% vs 81.1% respectively). Compared with the Non-TFSP participants the TFSP participants had a smaller proportion of college degrees (10.1% vs 3.4% respectively). Monthly incomes for the majority (76.1%) of TFSP participants were less than $1000 birr ($45 US Dollars).

It was found that there were significant differences between the TFS and Non-TFS group in educational level (chi-square statistic=23.806, p=0.000), monthly income (chi-square statistic=16.967, p=0.000), and employment status (chi-square statistic=12.001, p=0.000). However, there were no significant differences between the two groups in terms of gender (chi-square statistic=0.166, P=0.684), age groups (chi-square statistic=5.575, 0.350), and marital status (chi-square statistic=6.044, P=0.302).

At the end of the twelve-month study period only 28.4% of the TFSP participants were not malnourished (had mean BMI values greater than 18.5 kg/m^2), but the majority (71.6%) of

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the TFSP participants were malnourished. The results also revealed that the TFSP participants were more likely to be severely or moderately malnourished. However, the percentage of severe malnutrition (BMI<16.0 kg/m^2) within the TFSP participants dropped from baseline (19.3%), to six months (8.0%), and twelve months (10.2%).

The relationship of participation in TFSP to food security was investigated. The results of chi square tests indicated that TFSP participants were more likely to be food insecure. Further, 88.7% of the TFSP participants, and 69.1% of the Non-TFSP participants had been food insecure. Only 11.4% of the TFSP participants and 30.9% of the Non-TFSP participants had been food secure.

Another key finding in this study was the lack of an association between TFSP participation and HIV disease stage. Table 10 shows that there were no significant differences in disease stage measures (CD4 cell count) between the TFSP and Non-TFSP groups. However, Table 9 shows that within TFSP participants the percentage of CD4 cell counts greater than or equal to 500cells/µl improved from baseline (25.8%), to six months (52.2%), and twelve months (53.3%).

Recommendations

Additional research on the TFSP, particularly with a focus on nutritional and health outcomes in HIV/AIDS patients, will enable us to understand better the impacts of TFSs on nutritional status and health outcomes. Many studies have shown the need for nutrition interventions to improve the nutritional status of HIV-infected patients, especially those who are undernourished (BMI<18.5kg/m^2), food insecure, and those whose CD4 cell counts are less than 500 cells/µl (Chege et al., 2016; Thapa et al., 2015; Palermo, et. al., 2013; Sunguya et al., 2012). Therefore, The Ethiopian Ministry of Health and other organizations should:

(1) Emphasize improved access to therapeutic food supplements, and improved nutritional services and benefits to people living with HIV;

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(2) Investigate and clearly define all possible factors related to nutrition program failure in this patient population;

(3) Place emphasis on more studies concerning the impacts of a therapeutic food supplement support program on nutrition and health outcomes in HIV/AIDS patients;

(4) Develop and implement appropriate food security programs for the HIV-infected population in Ethiopia;

(5) Give proper counseling and clear instructions to patients to remove obstacles to TFS intake treatment adherence;

(6) Enact policies to promote the consumption of protein- and micronutrient-rich foods such as legumes, ground nuts, and lentils, in addition to TFSs;

(7) Maintain adequate TFS stores to ensure a reliable supply of TFS to the malnourished HIV infected in- and out-patients;

(8) Develop a set of HIV treatment adherence tools (electronic reminder devices) such as alarms clock, mobile, computer, and the like Reminder tools minimizes the risk of non-adherence to TFS intake among the TFSP participants due to forgetting;

(9) Target patients reporting histories of alcoholic beverage consumption, cigarette smoking, and illegal drug use in order to enhance adherence to TFS intake. It is anticipated that patients with these characteristics are less likely to adhere to their treatment regimens. Thames et al. (2012); Ortego et al. (2011); Arnsten (2007); and Chesney (2006) have reported that patients with histories of substance use and consumption of alcoholic beverages are more likely to exhibit higher rates of refusal of treatment, and are significantly less engaged with their health care providers.

Strengths of the Study

The results from our study may be used to improve and maximize potential benefits of TFSP to people living with HIV. This work will provide valuable information to the therapeutic food supplement program administrators by helping them to identify and target individuals at

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high food insecurity and nutritional risk. As far as can be determined this is the first study to characterize HIV-infected participants receiving TFS benefits, and to identify barriers to TFS intake among the TFS participants. In addition, our study is also the first to evaluate the program's effect on the nutrition and food security status, and health outcomes of HIV-infected people. Although the findings did not support most of the hypotheses, our findings provide an introduction to further studies investigating the benefits of a therapeutic food supplement support program on nutrition and health outcomes in HIV/AIDS Patients.

Limitations of the Study

The following are limitations to the current study.

(1) Regarding baseline nutrition and health status, the TFSP group and the Non-TFSP group did not begin the study at the same levels. A randomized controlled trial (RCT) would have been better, but was not feasible for ethical reasons. A RCT, in which the control group would not receive the TFS, would mean denying this treatment to patients in need of it.

(2) There is a possible patient selection bias for the TFSP. Some patients who were eligible for the TFSP were not placed on TFSP as part of their clinical HIV care treatment.

(3) Participants were recruited only from St. Paul's Hospital. Therefore the results cannot be generalized to all HIV-infected patients in Ethiopia. Nevertheless, this study shed light on the relationships between a therapeutic food supplement program on nutrition and health outcomes in TFSP and non-TFSP participants.

(4) The sample size in the intervention group was smaller than was desirable.

(5) The sample was also a convenience sample. Consequently, the results cannot be generalized to all HIV-infected patients in Ethiopia.

(6) Some data were incomplete. For example, some of the biochemical measure data such as viral load, and serum albumin were eliminated from inclusion in the study because the sample sizes for these variables were too small.

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(7) The author cannot vouch the validity of the biochemical tests results. It was assumed that the test results were accurate.

(8) Many variables involved self-reporting, including the food eaten in the past 12 months via the six-item short form of US household food security survey module questionnaire. The accuracy of self-report data could be questioned.

(9) Adherence to TFS intake was assessed only in terms of missing TFS doses. Other dimensions of adherence such as whether patients took ART drugs and other medicines in accordance with time and dietary instructions were not available.

(10) It is possible there might be a selection bias, as selection process includes only adults of aged 18 years and older who were available for recruitment.

(11) The findings of the study indicated that participation in a therapeutic food supplement support program by itself cannot give significant improvements in nutritional status and health outcomes due to differences in patients' food security and disease stage during the study period.

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APPENDICES

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Appendix A: Project Time Line

	2016 year											2017 year										
	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Supervisor visit	x																						
Literature Review		x	x	x	x	x	x	x															
Formulation of Hypothesis & Objectives				x	x																		
Design of Methodology					x	x																	
Contacting with selected health care institute (St. Paul's Hosp. Addis Ababa, Ethiopia)					x	x			x	x	x	x	x	x									
Selection of subjects from the institute.													x	x									
Main Study: Consent & data collection													x	x									
Data processing: data entry													x	x	x								
Data Analysis														x	x	x	x	x					
Discuss results with supervisor														x	x	x	x	x	x	x	x		
Final Report writing													x	x	x	x	x	x	x	x	x		

Appendix B: Approval of Study by Howard University Institutional Review Board

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HOWARD UNIVERSITY

Office of Regulatory Research Compliance

Date:	January 27, 2017
To:	Allan A. Johnson, Ph.D. Department of Nutritional Sciences
From:	The Office of Regulatory Research Compliance
Title:	**IRB-16-PNAH-27:** Factors Influencing the Impact of a Therapeutic Food Supplement Support Program on Nutrition and Health Outcomes in HIV/AIDS Patients
Approval Date:	**January 27, 2017**
Expiration Date:	**January 26, 2018**
Action:	Administrative Review- *New Student Research*

The revisions to the above-referenced submission was approved by administrative review on January 27, 2017. This submission was approved with administrative review during the January 18, 2017 IRB meeting. Approval for this study is through **January 26, 2018**.

Please be reminded of the following:

1. It is your responsibility to ensure that a continuing review report is submitted to the IRB in a timely manner. Should you anticipate renewing this protocol at the end of the approved time frame, please submit the C-2 Form **60 days prior to the expiration date** (Please note that this office will automatically terminate the project on the date stated above, unless reviewed and re-approved by the IRB.);
2. If you plan to close this protocol, a close-out report must be submitted to the IRB within 30 days after completion. Use an C-2 Form for this purpose as well; and
3. During the project period of this research, the IRB has the right to conduct a monitoring site visit and you will be given prior notice.
4. IRB date-stamped consent documents should be used when obtaining informed consent;
5. All informed consent documents must be kept on record with this project and should be archived by you for at least three (3) years after the last date of the IRB approval; and
6. Any changes including changes in personnel, modifications to the protocol and advertising must be reviewed and approved by the IRB prior to initiation.
7. The HU IRB Federal Wide Assurance number is FWA00000891.

Please refer to the above mentioned date and protocol number when making inquiries concerning this protocol.

CC: IRB File
Thomas O. Obisesan, M.D., MPH, F.A.A.F.P., AVP of Regulatory Research Compliance
Marline Brown-Walthall, MPH, Sr. Compliance Administrator
Mesfin Tadesse Anshebo, Student Investigator

HU Research Building I
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Appendix C: Consent Form

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CONSENT FOR INVESTIGATIVE PROCEDURES

HOWARD UNIVERSITY

WASHINGTON, DC 20059

1. **The following tests and/or procedures are needed for the project entitled:** Factors Influencing the Impact of a Therapeutic Food Supplement Support Program on Nutrition and Health Outcomes in HIV/AIDS Patients.

Tests and/or Procedures to be Performed

- Completion of interview schedule
- Collection of information from medical records (Biochemical measures - CD_4 count, viral load, hemoglobin, hematocrit, albumin; weight, height; therapeutic food supplement intake-initiation date, therapeutic supplement type).

2. **Explanation to the Participant**:

You are being asked to participate in a project conducted by Dr. Allan Johnson, a Professor in the Department of Nutritional Sciences at Howard University, and Mesfin Anshebo, a Ph.D. student in the Department of Nutritional Sciences at Howard University.

The purpose of the study is to investigate the impacts of taking therapeutic food supplements on food security, nutritional status, disease stage and perceived quality of life of people living with HIV and AIDS who are under ART. Additionally, the study will be used to identify factors (barriers) that influence adherence to therapeutic nutrition supplements. You are being asked to participate in this study because you have been diagnosed with this disease. Your name was obtained from St. Paul's Hospital, Addis Ababa, Ethiopia. This study is expected to be finished in December, 2016.

If you volunteer to participate in this study, I will ask you to provide about 30 minutes of your free time to answer some questions from the interview schedule. The interview schedule will ask you to provide information such as your socio-demographic characteristics (age, gender, educational level etc.), foods eaten in your household in the past 12 months, consumption of the therapeutic food supplement, and factors influencing your consumption of the therapeutic food supplement.

We do not expect any risk to you from your participation in the project, other than the possibility you may become uncomfortable answering some of the questions. However, you are free to not answer any question that may make you feel uncomfortable.

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JAN 26 2018

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You may or may not personally benefit from the study. However by being a subject in this study you will help in getting a necessary data for the study. The result of the study may be used to find out who to reach out to in order to increase access to therapeutic food supplements, and improve nutritional services and benefits to people living with HIV/AIDS.

All data collected from you will be kept confidential. No information that could be used to identify who you are will be associated with the data in any way.

You will not be compensated for your participation in the study.

All reasonable precautions have and will be taken to reduce risk(s) and to provide for your care.

You are free to withdraw from this study at any time without affecting either your right to receive on-going care or your relationship with St. Paul Hospital.

The Howard University Institutional Review Board will have access to the records of this project.

Dr. Allan Johnson (Principal Investigator) can be reached at the following number 202-806-7111 in the event you have any questions regarding your participation in this project and your research-related rights. You should contact him in the event of a research-related injury. You may also contact Mesfin Tadesse Anshebo at +251-965-190126 (Student Research Investigator) at any time for answers to pertinent questions about this research

If you have questions any time that you would like to discuss with someone other than the investigators on this project, you are free to contact the Howard University Institutional Review Board at 202-865-8597 between 8:30 a.m. and 5:00 p.m.

3. I have read the above description of the research project and anything I did not understand was explained to me by Mesfin Tadesse Anshebo and my questions were answered to my satisfaction. I agree to participate in the above-referenced project.

I acknowledge that I have received a personal copy of this consent form.

_____
Participant's Signature Date

4. I, the undersigned, have defined and fully explained the test(s) or procedure(s) involved in this investigation to the above participant or parent or guardian.

_____ _____
Investigator's Signature Date

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Appendix D: Interview Schedule

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Interview Schedule

ID Number: _____

Date Administered: _____

Title of the Study:

Factors Influencing the Impact of a Therapeutic Food Supplement Support Program on Nutrition and Health Outcomes in HIV/AIDS Patients.

I am conducting an interview about Therapeutic Food Supplements and ART. The interview schedule will ask you to provide information such as your socio-demographic characteristics (age, gender, educational level etc.), consumption of the therapeutic food supplement, factors influencing your consumption of the therapeutic food supplement, and your quality of life.

I will appreciate your participation in this interview. The information you provide will help to understand the impact of a therapeutic food supplements support program on nutrition and health outcome for the HIV infected, and help to plan health services. The interview takes between 20-30 minutes to complete. Whatever information you provide will be kept strictly confidential and will not be shown to other persons.

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These questions are about HIV infection status, ART drug treatment, and therapeutic food supplement intake status and how the drug and supplement have been with you during the past 12 months. For each question, please tell me the answer that applies to you.

1. When were you diagnosed as positive for HIV?

   Month____ **and** Year____

2. When did you start on the ART?

   Month____ **and** Year____

3. Are you on the therapeutic food supplement program?

   ____Yes ____No (If no, please skip to question 9)

4. If yes, when did you start on the therapeutic food supplement program?

   Month____ **and** Year____

5. How many doses of the therapeutic food supplement(s) are prescribed each day?

   ____doses

6. During the past week (last seven days) have you missed taking your therapeutic food supplement(s)?

   ____Yes ____No (If no, please skip to question 9)

6. If yes, how many time(s) did you miss taking your therapeutic food supplement(s) in the past week?

   ____times

7. Is there any reason why you have missed taking your therapeutic food supplement(s)?

   ____Yes ____No (If no, please skip to question 9)

8. If yes, what are the reasons you have missed taking your therapeutic food supplement(s)? (Check all that apply)

   ____There are side effects from the therapeutic food supplement(s)

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____I share the therapeutic food supplement(s) with others

____I forgot

____I felt better

____I was too ill

____I did not want anyone to know I was taking a therapeutic food supplement(s)

____It was out of stock at the drug store

____I ran out of therapeutic food supplement(s)

____I lost the therapeutic food supplement(s)

____delivery (not clear)

____travel problems (not clear)

____I was unable to pay for the therapeutic food supplement(s)

____I was drinking

____I was depressed

____Other (Please specify) _____

These next questions are about the foods eaten in your household in the past 12 months. First, I am going to read you two statements that people have made about their food situation. Please tell me whether the statement was often true, sometimes true, or never true for you or the other members of your household in the past 12 months.

9. The first statement is "the food that I/we bought just didn't last, and I/we didn't have money to get more". (Check one only)

____Often true

____Sometimes true

____Never true

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10. The second statement is "I/we couldn't afford to eat balanced meals".

(Check one only)

____Often true

____Sometimes true

____Never true

11. In the past 12 months, did you/you or other adults in your household ever cut the size of your meals or skip meals because there wasn't enough money for food?

____Yes ____No (If no, please skip to question 13)

12. If yes, how often did this happen? (Check one only)

____Almost every month

____Some months but not every month

____Only 1 or 2 months

13. In the past 12 months, did you ever eat less than you felt you should because there wasn't enough money to buy food?

____Yes ____No

14. In the past 12 months, were you ever hungry but didn't eat because you couldn't afford enough food?

____Yes ____No

The next section of the interview questions asks about important lifestyle characteristics that you may have experienced over the last weeks and months. We need to understand how people with HIV are really doing with their lifestyle characteristics. Please tell us what you are actually doing. We need to know what is really happening, not what you think we "want to hear".

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15. Do you consume any alcoholic beverages?

____Yes ____No

16. Do you use any illegal drugs?

____Yes ____No

17. Do you smoke cigarettes?

____Yes ____No

18. During the past twelve months, have you ever taken any of these appetite stimulants?

____Yes ____No

The next interview questions asks about your background characteristics

19. How old are you?

____years

20. Gender

____Male

____Female

21. What is your marital status? (Check one only)

____Never married

____Married

____Widowed

____Separated

____ Divorced

____Living together with a partner

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22. What is the highest educational level you have completed? (Check one only)

____Primary School

____Middle School

____High School

____Some College

____College degree

____Other (Please specify) _____

____No education

23. Are you employed?

____Yes ____No

24. What is your monthly income? (Check one only)

____Less than 1000 birr

____1000-3000 birr

____More than 3000 birr

Thank you for taking the time to complete the questionnaire and support this work.

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DATA FROM THE MEDICAL REGISTER

25. Biochemical measures

- CD_4 count_____
- Viral load_____
- Hemoglobin_____
- Hematocrit_____
- Serum albumin_____

26. Type of antiretroviral medication.

_____nucleoside reverse transcriptase inhibitors (NRTIs);

_____non-nucleoside reverse transcriptase inhibitors (NNRTIs);

_____protease inhibitors (PIs);

_____fusion and entry inhibitors;

_____pharmacokinetic enhancers; and

_____Integrase strand transfer inhibitors (INSTIs). (FDA, 2016).

27. Type(s) of therapeutic food supplement(s)

Ready-to-Use Foods (RUFs): F-75, F-100, Plumpy Nut, Plumpy sup, other (will be identified and taken from the patient chart)

_____

_____

28. Anthropometric measures

Weight (kg) _____

Height (m) _____

BMI (calculated) (kg/m^2) _____

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Appendix E: Ethical Clearance-St. Paul's Millennium Medical College, Addis Ababa

Date: 17/2/2017

Ref. No. pm23/129

Institutional Review Board (IRB) of St. Paul's Hospital Millennium Medical College (SPHHMC)

Ethical Clearance

Research Title: - Factors Influencing the Impact of a Therapeutic Food Supplement Support Program on Nutrition and Health Outcomes in HIV/AIDS Patients

Principal Investigator: - Mesfin Tadesse

The IRB of SPHMMC has reviewed the above mentioned research proposal and made the following decision:

1. Approved:- ✓
2. Approved with recommendation:- _____
3. Approved on condition :-_____
4. Disapproved:- _____

The decision is valid for 12 months and the research should be conducted in compliance with the protocol/proposal approved by the IRB of SPHMMC. Any subsequent revision/amendment of the protocol/proposal needs approval before conduct of the research. The researcher should also submit written summaries of the research status to the IRB every 03 months. Upon the conclusion of the study, manuscripts and thesis work to the final/completed research project needs to be submitted to the IRB.

IRB Chair: Dr Birke Anbesse

Signature: _____

Date: February 17, 2017

Cc:

- Vice Provost for Academic and Research
- IRB
- Mesfin Tadesse
  SPHMMC

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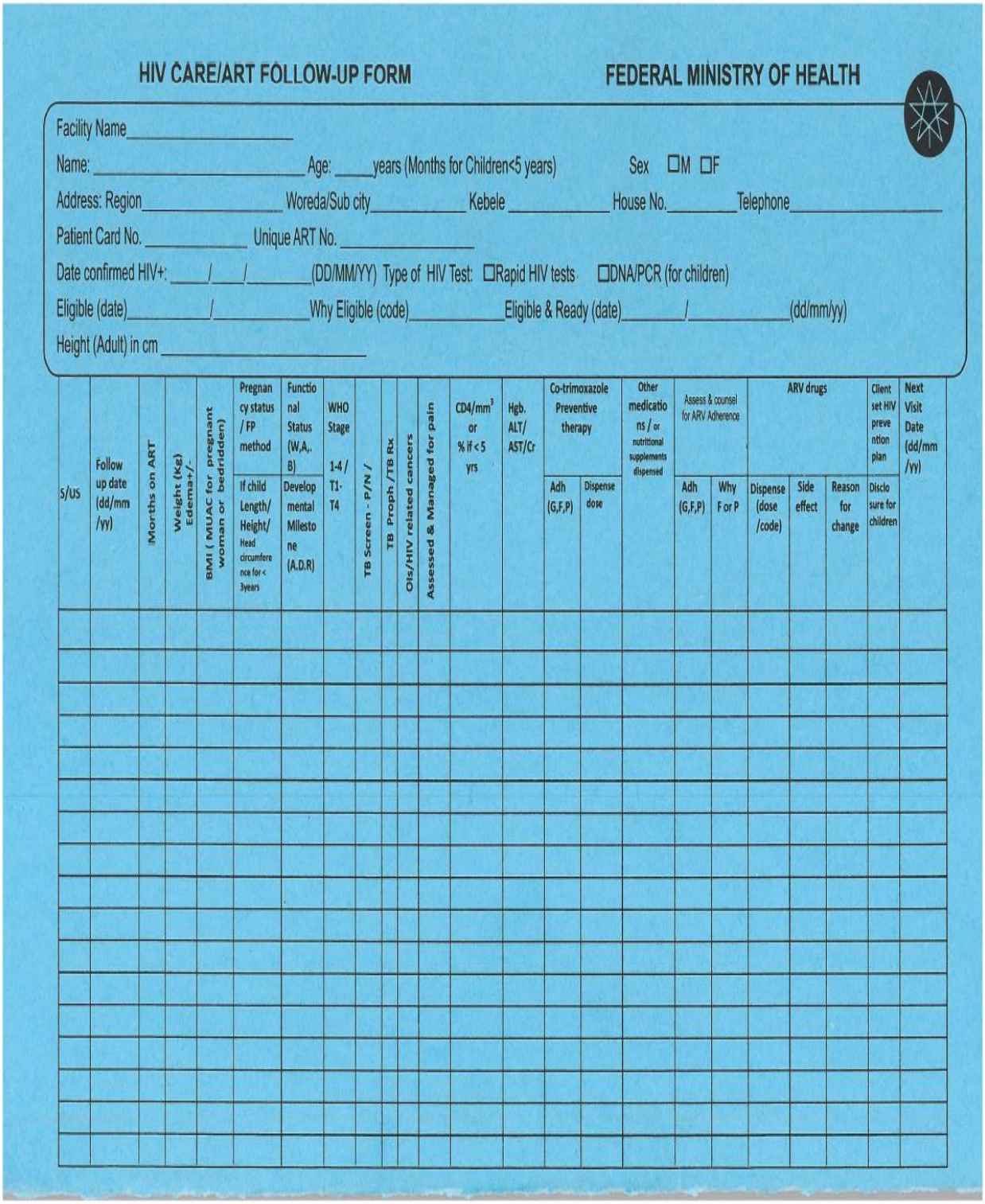
Appendix F: HIV Care/ART Follow-Up Form



HIV CARE/ART FOLLOW-UP FORM

FEDERAL MINISTRY OF HEALTH

Facility Name_____

Name: _____ Age: _____years (Months for Children<5 years) Sex ☐M ☐F

Address: Region_____ Woreda/Sub city_____ Kebele _____ House No._____Telephone_____

Patient Card No. _____ Unique ART No. _____

Date confirmed HIV+: ____/____/_____(DD/MM/YY) Type of HIV Test: ☐Rapid HIV tests ☐DNA/PCR (for children)

Eligible (date)_____/_____Why Eligible (code)_____Eligible & Ready (date)_____/_____(dd/mm/yy)

Height (Adult) in cm _____

s/Us	Follow up date (dd/mm /yy)	iMorths on ART	Weight (Kg) Edema+/-	BMI (MUAC for pregnant woman or bedridden)	Pregnancy status / FP method	Functional Status (W,A,. B)	WHO Stage 1-4 / T1- T4	TB Screen - P/N /	TB Proph /TB Rx	OIs/HIV related cancers	Assessed & Managed for pain	CD4/mm³ or % if < 5 yrs	Hgb. ALT/ AST/Cr	Co-trimoxazole Preventive therapy		Other medications / or nutritional supplements dispensed	Assess & counsel for ARV Adherence		ARV drugs			Client set HIV prevention plan	Next Visit Date (dd/mm /yy)
					If child Length/ Height/ Head circumference for < 3years	Developmental Milestone (A.D.R)								Adh (G,F,P)	Dispense dose		Adh (G,F,P)	Why F or P	Dispense (dose /code)	Side effect	Reason for change	Disclosure for children	

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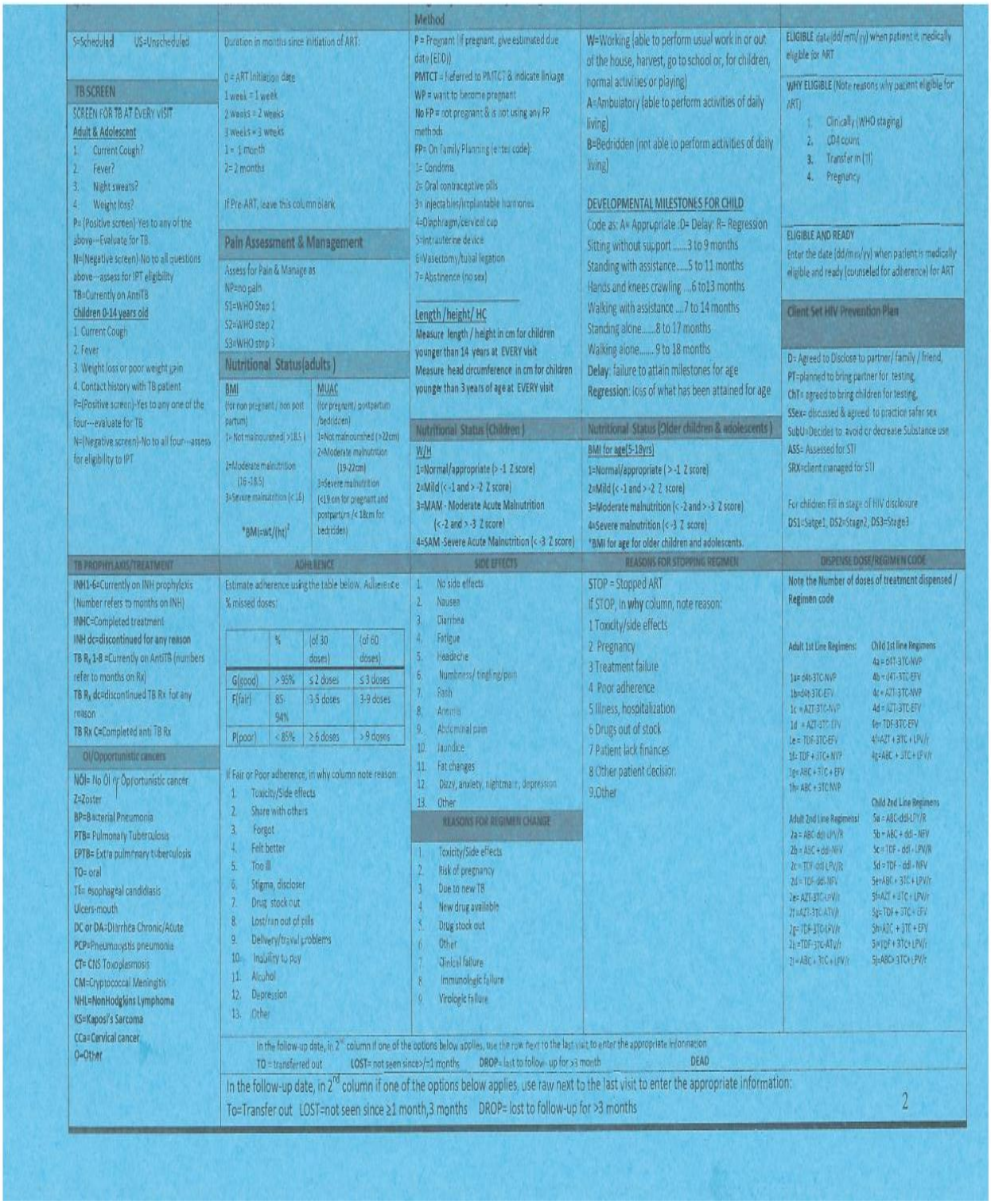

S=Scheduled US=Unscheduled

TB SCREEN

SCREEN FOR TB AT EVERY VISIT

Adult & Adolescent

1. Current Cough?
2. Fever?
3. Night sweats?
4. Weight loss?

P= (Positive screen)-Yes to any of the above---Evaluate for TB.

N=(Negative screen)-No to all questions above---assess for IPT eligibility

TB=Currently on AntiTB

Children 0-14 years old

1. Current Cough
2. Fever
3. Weight loss or poor weight gain
4. Contact history with TB patient

P=(Positive screen)-Yes to any one of the four---evaluate for TB

N=(Negative screen)-No to all four---assess for eligibility to IPT

Duration in months since initiation of ART:

0 = ART Initiation date
1 week = 1 week
2 Weeks = 2 weeks
3 Weeks = 3 weeks
1 = 1 month
2= 2 months

If Pre-ART, leave this column blank

Pain Assessment & Management

Assess for Pain & Manage as
NP=no pain
S1=WHO Step 1
S2=WHO step 2
S3=WHO step 3

Nutritional Status(adults)

BMI	MUAC
(for non pregnant / non post partum)	(for pregnant/ postpartum /bedridden)
1= Not malnourished(>18.5)	1=Not malnourished (>22cm)
2=Moderate malnutrition (16-18.5)	2=Moderate malnutrition (19-22cm)
3=Severe malnutrition (<16)	3=Severe malnutrition (<19 cm for pregnant and postpartum /<18cm for bedridden)

*BMI=wt/(ht)^2

Method

P = Pregnant (If pregnant, give estimated due date (EDD))
PMTCT = Referred to PMTCT & indicate linkage
WP = want to become pregnant
No FP = not pregnant & is not using any FP methods
FP= On Family Planning (enter code):
1= Condoms
2= Oral contraceptive pills
3= injectables/implantable hormones
4=Diaph/agm/cervical cup
5=Int-uterine device
6=Vasectomy/tubal legation
7= Abstinence (no sex)

Length /height/ HC

Measure length / height in cm for children younger than 14 years at EVERY visit
Measure head circumference in cm for children younger than 3 years of age at EVERY visit

Nutritional Status (Children)

W/H
1=Normal/appropriate (> -1 Z score)
2=Mild (< -1 and > -2 Z score)
3=MAM - Moderate Acute Malnutrition (<-2 and > -3 Z score)
4=SAM -Severe Acute Malnutrition (< -3 Z score)

W=Working (able to perform usual work in or out of the house, harvest, go to school or, for children, normal activities or playing)
A=Ambulatory (able to perform activities of daily living)
B=Bedridden (not able to perform activities of daily living)

DEVELOPMENTAL MILESTONES FOR CHILD

Code as: A= Appropriate :D= Delay: R= Regression
Sitting without support.....3 to 9 months
Standing with assistance.....5 to 11 months
Hands and knees crawling ....6 to13 months
Walking with assistance ....7 to 14 months
Standing alone.....8 to 17 months
Walking alone.....9 to 18 months
Delay: failure to attain milestones for age
Regression: loss of what has been attained for age

Nutritional Status (Older children & adolescents)

BMI for age(5-19yrs)
1=Normal/appropriate (> -1 Z score)
2=Mild (< -1 and > -2 Z score)
3=Moderate malnutrition (< -2 and > -3 Z score)
4=Severe malnutrition (< -3 Z score)
*BMI for age for older children and adolescents.

ELIGIBLE date(dd/mm/yy) when patient is medically eligible for ART

WHY ELIGIBLE (Note reasons why patient eligible for ART)
1. Clinically (WHO staging)
2. CD4 count
3. Transfer in (TI)
4. Pregnancy

ELIGIBLE AND READY
Enter the date (dd/mm/yy) when patient is medically eligible and ready (counseled for adherence) for ART

Client Set HIV Prevention Plan

D= Agreed to Disclose to partner/ family / friend,
PT=planned to bring partner for testing,
ChT= agreed to bring children for testing,
SSex= discussed & agreed to practice safer sex
SubU=Decides to avoid or decrease Substance use
ASS= Assessed for STI
SRX=client managed for STI

For children Fill in stage of HIV disclosure
DS1=Satge1, DS2=Stage2, DS3=Stage3

TB PROPHYLAXIS/TREATMENT

INH1-6=Currently on INH prophylaxis (Number refers to months on INH)
INHC=Completed treatment
INH dc=discontinued for any reason
TB R_x 1-8 =Currently on AntiTB (numbers refer to months on Rx)
TB R_x dc=discontinued TB Rx for any reason
TB Rx C=Completed anti TB Rx

OI/Opportunistic cancers

NOI= No OI ry Opportunistic cancer
Z=Zoster
BP=Bacterial Pneumonia
PTB= Pulmonary Tuberculosis
EPTB= Extra pulmonary tuberculosis
TO= oral
TE= esophageal candidiasis
Ulcers-mouth
DC or DA=Diarrhea Chronic/ACute
PCP=Pneumocystis pneumonia
CT= CNS Toxoplasmosis
CM=Cryptococcal Meningitis
NHL=NonHodgkins Lymphoma
KS=Kaposi's Sarcoma
CCa=Cervical cancer
O=Other

ADHERENCE

Estimate adherence using the table below. Adherence % missed doses:

	%	(of 30 doses)	(of 60 doses)
G(good)	>95%	≤ 2 doses	≤ 3 doses
F(fair)	85-94%	3-5 doses	3-9 doses
P(poor)	< 85%	≥ 6 doses	> 9 doses

If Fair or Poor adherence, in why column note reason:
1. Toxicity/Side effects
2. Share with others
3. Forgot
4. Felt better
5. Too ill
6. Stigma, discloser
7. Drug stock out
8. Lost/ran out of pills
9. Delivery/travel problems
10. Inability to pay
11. Alcohol
12. Depression
13. Other

SIDE EFFECTS

1. No side effects
2. Nausea
3. Diarrhea
4. Fatigue
5. Headache
6. Numbness/ tingling/pain
7. Rash
8. Anemia
9. Abdominal pain
10. Jaundice
11. Fat changes
12. Dizzy, anxiety, nightmare, depression
13. Other

REASONS FOR REGIMEN CHANGE

1. Toxicity/Side effects
2. Risk of pregnancy
3. Due to new TB
4. New drug available
5. Drug stock out
6. Other
7. Clinical failure
8. Immunologic failure
9. Virologic failure

REASONS FOR STOPPING REGIMEN

STOP = Stopped ART
If STOP, in why column, note reason:
1 Toxicity/side effects
2 Pregnancy
3 Treatment failure
4 Poor adherence
5 Illness, hospitalization
6 Drugs out of stock
7 Patient lack finances
8 Other patient decision
9.Other

DISPENSE DOSE/REGIMEN CODE

Note the Number of doses of treatment dispensed / Regimen code

Adult 1st Line Regimens:
1a= d4t-3TC-NVP
1b=d4t-3TC-EFV
1c = AZT-3TC-NVP
1d = AZT-3TC-EFV
1e = TDF-3TC-EFV
1f= TDF + 3TC + NVP
1g= ABC + 3TC + EFV
1h= ABC + 3TC-NVP

Child 1st line Regimens
4a = d4T-3TC-NVP
4b = d4T-3TC-EFV
4c = AZT-3TC-NVP
4d = AZT-3TC-EFV
4e= TDF-3TC-EFV
4f=AZT + 3TC + LPV/r
4g=ABC + 3TC+ LPV/r

Adult 2nd Line Regimens:
2a = ABC-ddI-LPV/R
2b = ABC + ddI-NFV
2c = TDF-ddI-LPV/R
2d = TDF-ddI-NFV
2e= AZT-3TC-LPV/r
2f =AZT-3TC-ATV/r
2g= TDF-3TC-LPV/r
2h=TDF-3TC-ATV/r
2i = ABC + 3TC + LPV/r

Child 2nd Line Regimens
5a = ABC-ddI-LPV/R
5b = ABC + ddI - NFV
5c = TDF - ddI - LPV/R
5d = TDF - ddI - NFV
5e=ABC + 3TC + LPV/r
5f=AZT + 3TC + LPV/r
5g= TDF + 3TC + EFV
5h=ABC + 3TC + EFV
5i=TDF + 3TC+ LPV/r
5j=ABC+ 3TC+ LPV/r

In the follow-up date, in 2nd column if one of the options below applies, use raw next to the last visit to enter the appropriate information
TO = transferred out LOST= not seen since>/=1 months DROP= lost to follow-up for >3 month DEAD

In the follow-up date, in 2nd column if one of the options below applies, use raw next to the last visit to enter the appropriate information:
To=Transfer out LOST=not seen since ≥1 month,3 months DROP= lost to follow-up for >3 months

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APPENDIX G: Studies on HIV prevalence ratio (female/male) in Ethiopia

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Source	HIV prevalence (%)		HIV prevalence Ratio (female/male)	Target population & Sample size
	Female	Male		
AIDS 1998, 12:315-322	6.9	6.0	1.2	Community-based study (n=3800)
Ethiop Med J, 39, 83-87, 2001	9.5	5.4	1.7	Police recruits (n=408)
JHPN, 2005, 23(4):358-368	12.4	8.5	1.4	Factory workers (n=1700)
AIDS in Ethiopia 5th report	19.5	14.4	1.4	VCT clients (n=26,000)
Aids in Ethiopia 6th Edition	15.7	11.6	1.4	VCT clients (n=564, 351)
Aids in Ethiopia 6th Edition	6.7	4.5	1.5	Blood donors (n=28, 539)
EDHS 2005, Urban	7.7	2.4	3.2	General urban population
EDHS 2005, Rural	0.6	0.7	0.86	General rural population
EDHS 2005, Total	1.9	0.9	2.1	General population

Source: HAPCO and GAMET. (2008)

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APPENDIX H: Daily Energy and Protein Requirements

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Group	HIV negative	HIV positive		
	Energy (kcal/day)	Asymptomatic (not displaying symptoms) (kcal/day)	Symptomatic (displaying symptoms) (kcal/day)	Protein (g/day)
Men				
Average active	2430	2670	2910–3160	57
Women				
Average active	2170	2400	2600–2820	48
Pregnant	2460	2710	2950–3200	55
Lactating	2570	2830	3080–3340	68
Children				
6–11 months old	730	800	880–950	10
1–3 years old	1250	1380	1500–1630	25
2–5 years old	1500	1650	1800–1950	26
5–10 years old	1800	1980	2160–2340	35
Boys				
10–14 years old	2360	2600	2830–3070	64
15–18 years old	2800	3080	3360–3640	84
Girls				
10–14 years old	2040	2240	2450–2650	62
15–18 years old	2100	2310	2520–2730	65

Source: WHO, 1993

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APPENDIX I: Micronutrient Level of Plumpy Nut

Nutrient	Unit	Nutrients per 100g
Vitamin A	mg re	0.95
Vitamin B1 (thiamine)	mg	0.5
Vitamin B2 (riboflavin)	mg	0.6
Niacin (B3)	mg NE	5.0
Vitamin B6	mg	0.6
Vitamin B12	mg	0.0016
Folate	mg DFE	0.034
Vitamin C	mg	50.00
Vitamin D	mg α-TE	0.0175
Vitamin E	mg	20.00
Vitamin K	mg	0.0225
Iodine	mg	0.1050
Copper [2]	mg	1.6
Iron	mg	12.00
Zinc	mg	12.5
Phosphorus [2]	mg	450.0
Magnesium	mg	110.0
Calcium	mg	450.0
Potassium [2]	mg	1250.0
Selenium	mg	00.025
Sodium [2]	mg	290.0

Source: (MOH , 2010)

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APPENDIX J: Primary Studies on use of RUTF Supplementation as part of Nutrition Intervention

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Author and Date	Participant No.	Duration	Location	Supplement	Weight gain	BMI increase	ART adherence
Cantrell et al (2008)	636	11 months	Zambia	CSB	6.3 kg	N/A	High
Ndekha et al (2009)	491	3 ½ months	Malawi,	RUFS vs. CSB	5.6 kg RUFS; 4.3 kg CSB	2.2 kg/m^2 RUFS; 1.7 kg/m^2 CSB	High
Bahwere et al. (2009)	60	3 months	Malawi	Local RUTF	2.5 kg	0.8 kg/m^2	N/A
Ahoua et al. (2011)	1106	29 months	Kenya and Uganda	RUTF Plumpy'Nut ®	4 kg	1.7 kg/m^2	N/A
Oosterhout and Ndekha (2009).	593	6 ½ months	Malawi	RUFS vs. CSB	6.9 kg RUFS; 6.8 kg CSB	2.7 kg/m^2 RUFS; 2.6 kg/m^2 CSB	High
Bowie et al (2005)	360	14 months	Malawi	WFP food basket	N/A	0.46 kg/m^2	N/A
Rawat et al. (2014)	904	12 months	Uganda	WFP food basket	N/A MUAC 6.7 mm	0.6 kg/m2	N/A

SOURCE: Audain et al., (2015)

CSB: Corn-Soy-Blend

RUFS: Ready-to-Use-Fortified-Spread

RUTF: Ready-to-Use-Therapeutic –Food

WFP: World Food Programme

MUAC: Mid-Upper-Arm-Circumference

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