Effectiveness of supplementary feeding for wasted people living with HIV/AIDS on antiretroviral therapy in Rwanda

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Effectiveness of supplementary feeding for wasted people living with HIV/AIDS on antiretroviral therapy in Rwanda

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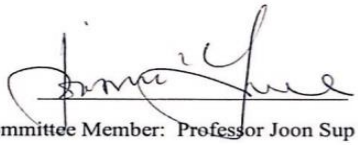

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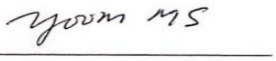

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Content

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Abbreviation	Full form
%	Percentage
AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-Retroviral Therapy
BMI	Body Mass Index
BMD	Bone mineral density
CSB	Corn-soy-blend
CM	Centimeter
CNLS	Commission National de Lutte Contre le SIDA
CD4	A cluster of Differentiation 4
DHA	Docosa-Hexanoic Acid
FANTA	Food and Nutrition Technical Assistance
FAO	Food Agriculture Organization
FCS	Food Consumption Scores
F100	Formula 100
F75	Formula 75
HIV	Human Immunodeficiency Virus
HFIAS	Household Food Insecurity Access Scale
ICU	Intensive Care Unit
KG	Kilogram
LNS	Lipid-based Nutrient Supplements
M	Meter
M^2	Meter square

MoH	Ministry of Health
MUAC	Mid-Upper Arm Circumference
OIs	Opportunistic Infections
PLWHA	People Living With HIV/AIDS
QoL	Quality of Life
RUTF	Ready-to-Use Therapeutic Food
SPSS	Statistical Package for Social Scientists
TG	Triglyceride
UN	United Nations
UNICEF	United Nations International Children's Emergency Fund
USAID	United States Agency for International Development
WFP	World Food Program
WHO	World Health Organization

Abstract

Introduction: Underweight is still prevalent in people living with HIV/AIDS (PLWHA) in resource-limited countries like Rwanda. Low body mass index (BMI), mid-upper arm circumference (MUAC) and Z-score below minus three (<-3) are strong risk factors of mortality and morbidity in PLWHA on antiretroviral therapy (ART). In Rwanda, nutrition supplements became a core standard and integrated with HIV care to manage the wasting syndrome seen in PLWHA starting ART. This study aimed to assess the effectiveness of fortified corn-soy blend (CSB^+) supplements in improving the nutrition status of PLWHA with wasting syndrome.

Methods: The retrospective cohort study was conducted to assess the nutritional status of 149 PLWHA with wasting managed with consecutive ART and nutrition support for a period of six months. The nutritional status of the subjects was determined by BMI and MUAC. BMI below 18.5 kilograms per meter squared (kg/m^2) and MUAC below 21cm were defined as underweight according to the World Health Organization (WHO) guidelines.

Results: A total of 149 PLWHA were included in the analysis. The mean BMI of 149 PLWHA improved with CSB^+ supplementation during the six month study period (17.448±0.546 to 18.631±0.535 kg/m^2, P =<0.001). This improvement in BMI was evident in both males (N=53, 17.2±0.53 to 21.9±24.4 kg/m^2, P=<0.001) and females (N=72, 17.5±0.53 to 18.6±0.52 kg/m^2, P=<0.001). The mean MUAC of 18.47±0.455 cm increased to 20.40±0.532 cm (P <0.001) in the sixth month with CSB^+ supplementation. At the end of six months, the overall prevalence of malnutrition decreased (P =0.306) and it was 36.0% and 66.7% as assessed by BMI and MUAC, respectively. The minimum time required to restore healthy BMI (≥18.5 kg/m^2) was at least six months.

Conclusion: Our study suggests that supplements improve the overall nutrition status of PLWHA with wasting syndrome and at least six months of nutritional supplements are required for BMI recovery. Further studies are needed to assess the level of food security and safety in the households of PLWHA to enable early interventions with supplementary feeding.

Keywords: antiretroviral, effectiveness, HIV/AIDS, wasting, Rwanda, supplements.

1 Introduction

1.1 Definition of key terms pertinent to the study.

Assessment is the qualified opinion of a healthcare provider informed by patient, Feedback and examination results, with regard to a specific issue, whether critical, pending or routine [1].

Antiretroviral is a drug used to prevent a retrovirus, such as HIV, from replicating [2].

Antiretroviral therapy is the daily use of a combination of HIV medicines to treat HIV infection [2].

Body mass index (BMI) is a measure of body fat based on weight adjusted for height, calculated as weight in kilograms divided by the square of height in meters (kg/m^2) [3]. BMI (kg/m^2) = Body weight (kg) / [Height (m^2)].

Effectiveness is the ability to be successful and produce the intended results at the degree to which objectives are achieved and the extent to which targeted problems are solved [4].

Food security exists when all people, at all times, have physical, social, and economic access to sufficient, safe, and nutritious food that meets their food preferences and dietary needs for an active and healthy life [5].

Malnutrition is nutritional disorders that result when the intake of essential macronutrients and micronutrients does not meet or exceeds the metabolic demands for those nutrients [6].

Undernutrition is a situation in which the body's requirements are not met, due to under-consumption, or to impaired absorption and use of nutrients. Undernutrition commonly refers

to a deficit in energy intake, but can also refer to deficiencies of specific nutrients, and can be either acute or chronic [7].

Wasting is a malnutrition status that caused by an involuntary loss of more than 10% of body weight (especially muscle mass) that reflects low Body Mass Index less than 18.5 kg/ m^2or Mid-Upper Arm-Circumference less than 21cm [8].

Supplementary feeding is a process of giving planned additional nutrients' density food or nutrients that are added to the usual daily diets intake [9].

Food Supplements are foodstuffs that are meant to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities, where nutrients could be vitamins, minerals, herbal extracts and other ingredients [10].

Wasting syndrome is a progressive involuntary loss of more than 10% of body weight (especially muscle mass) and it is HIV/ AIDS-associated defining condition [11].

1.2 Background of the Study

Between 2010 and 2017, the global incidence and death rates associated with HIV/AIDS have declined by 16% and 34% in all age groups [12]. A sharp decline in AIDS-related deaths by 64% occurred in 2016 with the initiation of ART for HIV/AIDS individuals and accelerated comprehensive packages of care in Eastern and Southern Africa reflect decline worldwide. However, the target for the 2020 milestone of less than 500, 000 new HIV infections and related deaths per year is yet to be attained [13].

In particular, the HIV/AIDS epidemic persists in populations with endemic undernutrition [14]. The HIV/AIDS epidemic has had a devastating impact on health, nutrition, food security and overall socioeconomic development in affected countries [5]. Even with an improved understanding of the interconnectedness between HIV/AIDS, undernutrition, and food insecurity over the past several decades [16], wasting syndrome or undernutrition continues to cause the epidemic proportion of HIV/AIDS-related deaths in resources limited countries [17]. Therefore, nutrition has regarded as a fundamental part of the comprehensive packages of care and support for people living with HIV/AIDS worldwide [6].

The relation between nutrition and HIV/AIDS infection are well known, good nutrition is very important for helping the body to fight against infection and opportunistic diseases by strengthening immunity[6]. Proper nutrition and balanced diets are essential for PLWHA to make up the loss of macronutrients and micronutrients caused by HIV/AIDS or opportunistic infections [18].

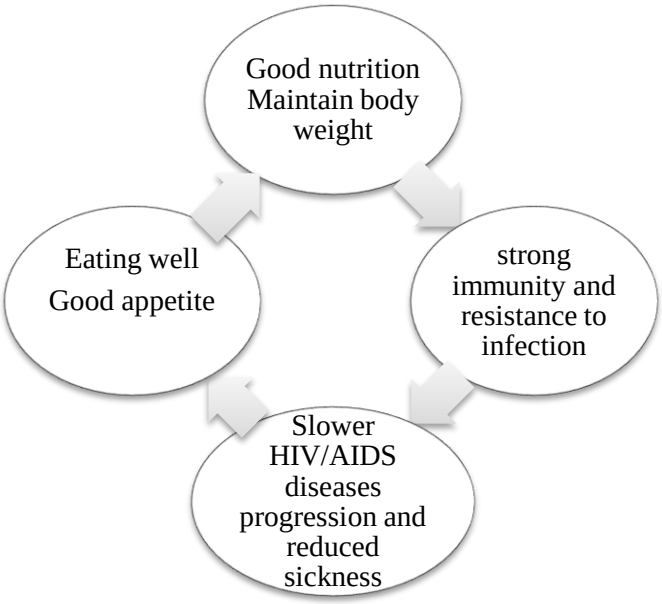

Figure 1.Relationship between good nutrition and HIV/AIDS [18]

Integration of nutrition service and HIV/AIDS care are keys important to tackle the undernutrition problem among PLWHA. Routine Nutrition assessment and screening; prescription of targeted nutrition supplements, education and counseling and food support are important parts of comprehensive packages of care for PLWHA, particularly in resources - limited countries where undernutrition and food insecurity are common [19].

A recent study done in Malawi about the prevalence of undernutrition for PLWHA showed that 95% of children HIV positive had severe acute malnutrition and high viral load with opportunistic infections. Therefore, the ministry of health (MoH) Malawi strengthened

nutrition and HIV care integration to deal with that problem[20]. Food assistance and nutrition supplements programming as part of the standard of care for PLWHA improve their nutrition status [19]. Failing to meet nutritional needs may lead to decreased immunity and increase susceptibility to opportunistic infections (OIs), which can lead to further malnutrition [21].

Besides, nutrient intake can improve antiretroviral absorption and tolerance. Therefore, appropriate nutrition can help improve PLWHA's quality of life (QoL) [22]. HIV infection leads to nutritional deficiencies through decreased food intake, mal-absorption, increased utilization and excretion of nutrients. This can cause severe wasting syndrome and hasten death later [23]. Wasting syndrome is one of the most visible signs of malnutrition as the patient's progress from HIV to AIDS. HIV infection affects nutritional status by increasing energy requirements, reducing food intake, and adversely affecting nutrients absorption and metabolism [24].

Nutritional supplementation program has become core standard of HIV care components for people living with HIV/AIDS(PLWHA) starting ART in resources limited countries like Rwanda, since low body mass index (BMI), Z-score and MUAC are strong risk factors for early mortality during antiretroviral therapy (ART), [25]. Such food assistance and nutrition supplements aim to improve the nutrition status of PLWHA. Despite such improvements in nutrition supplements programs, undernutrition and food insecurity of the PLWHA are still prevalent in developing countries like Rwanda.

In Rwanda, current HIV/AIDS prevalence is 3%, HIV new infections are reduced from 6,000 to 2,000 and HIV-related deaths are reduced from 5,000 to 2,500 by 2018 [26]. An estimate of 8% of PLWHA started antiretroviral therapy have wasting syndrome [27].

Despite such improvement in HIV/AIDS prevention and care is done in Rwanda, HIV/AIDS is still ranked seventh among the top 10 causes of death however deaths contributed by undernutrition are not yet known[28]. Since 2002, the government of Rwanda integrated full nutrition services into HIV/AIDS care packages, intending to reduce undernutrition by providing supplements such as fortified corn-soy-blend (CSB^+) and ready to use therapeutic food (RUTF) for PLWHA with wasting syndrome [29] [30].

So far, the researches on the nutrition status of PLWHA taking ART in Rwanda [31] have not assessed the effectiveness of supplements in improving the nutrition status in those with wasting syndrome. Therefore, this study aimed to assess the effectiveness of CSB^+ supplements in improving the nutrition status of underweight PLWHA on ART in Rwanda.

1.3 The purpose of the study

In this study, the nutrition status of PLWHA was assessed at ART initiation, at CSB^+ initiation, and after six months of CSB^+ supplementation. The factors associated with nutrition status improvements were also assessed. Finally, the minimum time required for restoring healthy BMI and MUAC in PLWHA by supplementation was determined. The findings of this study will help improving supplementation program and policies aim to reduce under-nutrition and its related risk factors including morbidity and premature deaths of PLWHA in Rwanda.

2 Literature Review

2.1 HIV, food security and undernutrition

Food security exists when all people, at all times, have physical, social, and economic access to sufficient, safe, and nutritious food that meets their food preferences and dietary needs for an active and healthy life [5]. HIV/AIDS affects the food security of individuals, households, and communities [32]. The crisis of HIV and climate change in sub-Saharan Africa affected negatively food security and productivity of the household. Therefore world food program (WFP) provided food support for vulnerable groups and families [33].

In Rwanda, severe food insecurity decreased from 78% to 49% while acceptable food consumption improved from 48% to 64% in general population by household food insecurity access scale (HFIAS) and household food consumption scores (FCS) programs [34]. Household food insecurity and inaccessibility are major causes of malnutrition and in HIV-infected patients like wasting syndrome for PLWHA in sub-Saharan Africa as well in Rwanda [10]. Undernutrition is a situation in which the body's requirements are not met, due to under-consumption, or to impaired absorption and use of nutrients.

Undernutrition commonly refers to a deficit in energy intake, but can also refer to deficiencies of specific nutrients, and can be either acute or chronic [7]. Undernutrition is most common in HIV patients in resource-limited countries and is mostly shown by low BMI<18.5kg/m^2, MUAC<21 cm and Z-score <-2. Routine nutrition screening and assessment and counseling should be done for early detection of malnutrition among HIV patients for rapid response[35].

Treatment of HIV infection with ARV may affect ⩾10% weight loss of subcutaneous fat due to inadequate nutrients intake and poverty [36]. Studies revealed that PLWHA who are underweight have risks of dying two to six times in their first six months of starting antiretroviral therapy treatment compared to those with normal body mass index [37].

2.2 HIV/AIDS and undernutrition cycle

Nutrition and HIV interact with each other in complex ways. HIV-induced immune-deficient individuals are at high risk of opportunistic infections that can worsen nutritional status and also HIV/AIDS affects nutrition by reducing food intake and mal-absorption of nutrients. On the other hand, undernutrition promotes HIV/AIDS progress quickly that reduces the quality of life[38]. Good nutrition supports overall health by helping to maintain the immune system and maintain a healthy weight, absorb HIV medicines and prevent opportunistic infectious diseases [39].

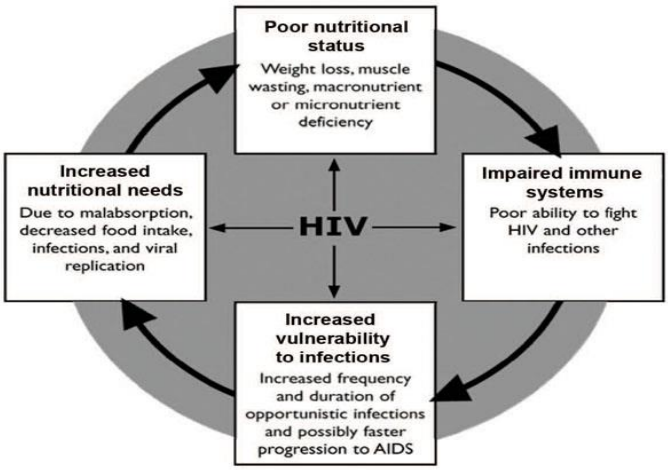

Figure 2: HIV and malnutrition cycle [40]

2.3 Nutrients, immunity and HIV infection

Micronutrients and micronutrient deficiency are common in HIV positive patients. ART initiation combined with food supplements improves nutrients for HIV patients' health[41]. PLWHA are at high risk of hypertriglyceridemia (polyunsaturated fatty acids) that reduce fasting serum triglyceride (TG) levels. Supplementation with docosahexaenoic acid (DHA) revealed to reduce fasting TG levels in antiretroviral-treated HIV-infected patients with mild hypertriglyceridemia and DHA tolerate minor GI symptoms and peripheral increase in DHA [42].

The use of synbiotic with nutrition treatment twice a day during six months proved to reduce gastrointestinal symptoms like diarrhea among PLWHA[4]. A nutritional formula was rich in protein and vitamins, minerals found to improve the quality of life of PLWHA in the intensive care unit (ICU) by increasing more than or equal to 1.3g/kg body weight in 72 hours and reduce the weight loss [43].

Decreased bone mineral density (BMD) was reported in HIV infected patients. HIV infected people develop osteoporosis frequently due to deficiency in calcium and vitamin D. Adequate supplements rich in calcium and vitamin D like other micronutrients and macronutrients are very important for HIV individuals ' lifetime[44,45]. Selenium is frequently deficient in HIV infected patients that have reduced immunological function and greater susceptibility to opportunistic infections. Long-term ART improves immunological function with increased selenium concentration for HIV patients [46].

2.4 Integration of nutrition service and HIV/AIDS Care

WHO recommended full packages of nutrition services to be integrated with the HIV care program to mitigate undernutrition in PLWHA patients who are on ART in resource-limited countries [20,47].

2.4.1 Safety nets target to HIV-affected households

Safety net programs include food, cash or vouchers, aim to cope with the socio-economic impacts of HIV. Food assistance programs provide food basket targeting to food insecure PLWHA and their households, and to people affected by the epidemic such as orphans and vulnerable children [16].

The duration of the food assistance usually ranging between 6 and 12 months, except for disabled and orphans where the duration of intervention may be longer. The core objectives of these programs tend to improve retention on ART and coping with the immediate socioeconomic impacts of HIV through improved food security in the short-term. A recent study done in Tanzania reported that food and cash assistance improved ART adherence and the nutrition status of people living with HIV/AIDS [48].

2.4.2 Nutrition supplementation program for HIV/AIDS patients

Nutrition supplements for people living with HIV aim to restore impaired nutrition status and prevent the progress of HIV associated comorbidities like opportunistic infections due to malnutrition. Adequate nutrient-dense foods and a balanced diet are quite important for HIV patients as well as healthy people [49].

Wasting syndrome is a common key factor that increases mortality and morbidity among PLWHA. It is caused by low energy intake compared to energy demands due to HIV and opportunistic infections, mal-absorption, intolerance and poverty [21].

Wasting syndrome defined by low body mass index (BMI) <18.5 kg/m^2, MUAC<21 cm and Z-score<-2SD and is a strong risk factor for early mortality during ART. The current classification of adults BMI that reflects health nutrition status consist of mild-to-moderately underweight (16.1kg/m^2≤BMI <18.4 kg/m^2 or BMI/Age-3<SD≤-2 SD), severely underweight (BMI ≤16 kg/m^2 , BMI/age≤-3SD); normal weight(18.5-24.9kg/m^2) , overweight (25≤29.9 kg/m^2) and obese B(MI≥30 kg/m^2) [50].

Nutrition treatment varies according to the type of underweight. Mild to moderate underweight are given a supplement CSB^+ (corn soya blend fortified), lipid-based nutrient supplements and RUTF (Ready to use therapeutic food) from three up to six months. Severe underweight should be provided with therapeutic milk such as Formula 100 and 75(F100, F75) and RUTF (Ready to use therapeutic food) [51].

The WHO guidelines recommend that therapeutic food or supplemental feeding should be given for a period of three months or longer until BMI is stabilized to normal (≥ 18.5 kg/m^2), MUAC ≥21 cm and Z-score≥-2SD [52].
For adults PLWHA, based on increased resting energy expenditure (REE), it is recommended that energy is increased by 10% than accepted to HIV negative people in asymptomatic phase and increases the energy intake of about 20% to 30% recommended during periods of symptomatic to maintain body weight [15].

Nutrition supplements and food support are important components of comprehensive care for PLWHA particularly for those with wasting syndrome and in areas where under-nutrition and food insecurity are endemic and common [53]. PLWHA are at high risk of nutritional deficiency at all stages of HIV disease. And Wasting syndrome of PLWHA is a strong predictor of early mortality and morbidity [14]. Recently, several studies assessed the role of supplements for HIV patients' nutrition status. Vitamin D deficiency was proved to diminish CD4 recovery after cART initiation that contributes to the poor clinical outcomes while vitamin A, selenium and sCD14 seen to increase CD4 recovery [54].

A study showed that a combination of ART and ready-to-use therapeutic food (RUTF) improve nutrition by recovering BMI or weight of wasted PLWHA patients. Meanwhile, adequate nutrition support is necessary to make up lost micronutrients and macronutrients for PLWHA [55]. Another study reported that the lipid-based nutrient supplements (LNS) and family maize was proved to reduce weight loss among HIV-infected breastfeeding women who were on ART [56].

2.4.3 Nutrition supplements program for HIV/AIDS patients in Rwanda

Rwanda like other resources limited countries integrated full package of nutrition services (nutrition assessment, screening, education and counseling, nutrition support) into HIV care packages for mitigating with wasting syndrome seen in PLWHA since 2002. The supplements commonly used in Rwanda are corn-soy blended fortified (CSB^{+}) and ready to use therapeutic food (RUTF) for HIV individuals with mild to moderated malnutrition while F100 and F75 are used as therapy for inpatients PLWHA with severe wasting syndrome [29].

Table 1.Nutrients composition of corn soya blend (CSB^{+}) per /100g of 7.5 kg[57]

Nutrients 'name	quantity	Nutrients' name	quantity
Dry mass of supplementary food (g)	143	Vitamin B-12 (µg)	3.3
Energy (kcal)	563	Vitamin C (mg)	145
Protein (g)	21	Vitamin D (µg)	8.1
Fat (g)	13	Vitamin E (mg)	12
Calcium (mg)	579	Vitamin K (µg)	161
Copper (mg)	0.7		
Iodine (µg)	57		
Iron (mg)	15		
Magnesium (mg)	190		
Phosphorus (mg)	396		
Potassium (mg)	1426		
Selenium (µg)	21		
Zing (mg)	11		
Folic acid (µg)	171		
Vitamin A (µg)	714		
Thiamine (mg)	0.8		
Riboflavin (mg)	1.2		
Niacin (mg)	11		
Pantothenic acid (mg)	11		
Vitamin B-6 (mg)	3.1		
Biotin (mg)	-		

Rwanda national nutrition protocol recommends that CSB^+ should be given during the period of three months for recovering weight lost with serving size of 250g/day that Provides 1,300 kcal/day, 14% protein and 31% fat and other nutrients [58]. So far, several studies assessed the nutrition status of PLWHA on ART in Rwanda has not yet assessed the effectiveness of supplements among those with wasting syndrome. Therefore, this study aimed to assess the effectiveness of CSB^+ supplement on nutrition status improvement of PLWHA with wasting syndrome on ART in Rwanda.

3 Methodology

3.1 Study population

The study population was 149 HIV/AIDS positive individuals with the moderate wasting syndrome who were on ART and received nutrition supplements for a period of six months in Kibilizi district Hospital and its catchment area, Rwanda.

3.1.1 Inclusion criteria

The following were the inclusion criteria for 149 participants.

1. HIV/AIDS positive individuals
2. Initiated ART
3. Had BMI range, $15.9 < BMI < 18.5 (kg/m^2)$
4. Had MUAC range, $17.4 < MUAC < 21cm$
5. They have been on nutrition support for six months consecutively.

3.1.2 Exclusion criteria

Underweight HIV/AIDS positive Individuals with incomplete or missing data were excluded

3.1.3 Primary outcomes

The mains outcome of interest for this study was recovering to normal nutrition status. Normal BMI was defined as weight for height squared (kg/m^2) that is ≥ 18.5 kg/m^2 and we compared MUAC for pregnant and lactating women to the normal cut off points which is $\geq$ 21 cm according to WHO guidelines [59].

3.1.4 Covariates

We included six covariates (ages, gender, height, marital status, social class (1, 2,3and 4) and occupation) to see if they were associated with nutrition improvements of the subjects during six months of the study period.

3.2 Study design

This retrospective cohort study assessed the nutrition status in a total of 149 PLWHA. All subjects were moderately underweight, on ART and received nutrition supplements for a period of six months, from January to June 2018.

3.3 Data sources and collection procedure

The data on nutrition indicators were collected retrospectively from the nutrition records of all subjects. The nutrition indicators included monthly assessment of weight for all subjects, MUAC for pregnant and lactating women, and Z-score for patients under 18 years. A questionnaire was designed to collect data such as age, sex, marital status, social class category, and occupation. Subjects were weighed using a calibrated mechanical Seca scale (Seca, North America), and their heights were measured in the standing position facing forward with the heels touching the wall using a tape measure (precision of 0.1 cm). MUAC was measured in cm using a tape.

Nutrition status was assessed and classified according to BMI that is calculated by division of weight (kg) by the square of height (m) and MUAC in cm. According to the WHO,16 kg/m^2 $\leq$ BMI <18.5 kg/m^2 and 17.4cm<MUAC<21 cm for lactating and pregnant women were classified as moderate underweight or moderate wasting [59].

3.4 Statistical analysis

All statistical analyses were performed using SPSS software, version 25 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to assess the prevalence of underweight and demographic characteristics of the study subjects. Continuous variables are presented as mean and SD. Categorical variables are presented as numbers and percentages. A student's t-test or ANOVA was used to determine the difference in mean BMI and MUAC according to factors (sex, marital status, social class, and occupation).

Chi-squared test was used to assess the differences in frequency of underweight according to sex, social class, occupation, and marital status. The student's t-test was used to compare the mean change in BMI and MUAC after supplementation. Extrapolation was applied to estimate the minimum time required for nutritional recovery (BMI $\geq$18.5 kg/m^2 or MUAC $\geq$21 cm). $P \leq 0.05$ was considered statistically significant.

4 Results

The study subjects included 149 PLWHA, of whom 53 (35.6%) were male and 96 (64.4%) were female, with age range of 18-64 years and mean age of 46.36 ± 9.88 years. In terms of marital status, 94 (63%) were married and 55 (37%) were single. In terms of profession, 104 (69.8%) were farmers but not professional farmers, 39 (26.2%) did not have a job and 6 (4%) had other jobs.

In terms of social classes that reflect economic status of household or wealth categories, 34 (22.8%) were in class 1 which means they were very poor, 62 (41.6%) were in class 2 which means they were moderate poor and 53 (35.6%) were in class which 3 means they were rich.

All participants lived in rural areas. Height at the initiation of ART was 162.85 ± 7.375 cm, and at the initiation of SCB^{+} was 162.9 ± 7.35 cm. At the time of ART initiation, CSB^{+} initiation and at the sixth month of supplement, mean weight were 53.31 ± 5.41 (kg), 46.81 ± 4.48 (kg) and 49.93 ± 4.28 (kg) respectively. Mean CD4 Results (/μL) Pre-ART and admission on ART was 443.17 ± 128.260 and at twelfth month on ART was 541.60 ± 138.51 (Table 2).

Table 2. General characteristics of wasted PLWHA who participated in the study

Variables	Total (N=149)
Age, years ,Mean ± SD(range)	46.36 ± 9.88 (18-64)
Height initiation of ART, cm	162.85 ± 7.375
Height at the initiation of CSB^+, cm	162.9 ± 7.35
Weight at the initiation of ART, kg	53.31 ± 5.41
Weight at the initiation of CSB^+, kg	46.81 ± 4.48
Weight at 6^{th} month of CSB^+, kg	49.93 ± 4.28
$CD4^+$ counts at the initiation of ART, μL	443.17 ± 128.26
$CD4^+$ counts at twelfth months on ART, μL	541.60 ± 138.51
Sex	
Male	53 (35.6)
Female	96 (64.4)
Marital status	
Married	94 (63.0)
Single	55 (37.0)
Social classes' category	
Class 1, very poor	34 (22.8)
Class 2, moderately poor	62 (41.6)
Class 3, rich	53 (35.6)
Occupation	
Farmer	104 (69.8)
No job	39 (26.2)
Other	6 (4.0)

Table 2: Data are presented as mean ± standard deviation or number of subjects (%)unless otherwise specified. PLWHA: people living with HIV/AIDS, SD: standard deviation, ART: antiretroviral therapy, CSB^{+}: fortified corn-soy-blend.

Among the total subjects, 19 (12.8%) were underweight (BMI <18.5 kg/m^2) at ART initiation. The prevalence of underweight did not vary significantly based on sex, marital status, or social class. Subjects with other jobs 3 (50%) were significantly underweight compared to those with no jobs 6 (15.4%) and farmers 10 (9.7%) (*P*=0.024) (Table 3).

Table 3. Body mass index classification at the initiation of antiretroviral therapy

Variables	BMI		P† value
	≥18.5 kg/m^2	<18.5 kg/m^2	
Total	130 (87.2)	19 (12.8)	
Sex			
Male	46 (86.8)	7 (13.2)	0.958†
Female	84 (87.5)	12 (12.5)	
Marital status			
Married	87 (92.5)	7 (7.5)	0.714†
Single	43 (78.2)	12 (21.8)	
Social classes category			
Class 1, very poor	29 (85.3)	5 (14.7)	
Class2, moderately poor	53 (85.5)	9 (14.5)	0.488†
Class 3, rich	49 (92.5)	4 (7.5)	
Occupation			
Farmer	94 (90.3)	10 (9.7)	
No job	33 (84.6)	6 (15.4)	0.024†
Other	3 (50.0)	3 (50.0)	

Table 3: N, (%) and P-value ($P^{\dagger}$) using Chi-square test.
Data are shown as the number of subjects and (%). BMI: body mass index,

The prevalence of malnutrition at the time of supplement initiation was 100%. After six months of supplementation, 80 subjects (64.0%) improved their nutrition status to normal (BMI ≥18.5 kg/m2) (*P*= 0.469). Based on MUAC, 8(33.3%) restored their nutrition status to normal (MUAC ≥ 21cm). Based on gender, 21(39.6%) and 22(33.3%) males and females respectively were still underweight according to BMI (*P*=0.469) (Table 4).

Table 4. Prevalence of underweight during the study period based on gender

Variables	Normal	Underweight	$P^{\dagger}$ value
BMI at CSB^{+} initiation			
Sex			
Total	0 (0.0)	125 (100)	
Male	0 (0.0)	53 (100)	
Female	0 (0.0)	72 (100)	
BMI in the sixth month of supplementation			
Total	80 (64.0)	45 (36.0)	
Male	32 (60.4)	21 (39.6)	
Female	48 (66.7)	24 (33.3)	$0.469^{\dagger}$
MUAC at CSB^{+} initiation			
Female	0 (0.0)	24 (100.0)	
MUAC at the sixth month of supplementation			
Female	8 (33.3)	16 (66.7)	

Table 4: N,(%) and † using the Chi-square test.

†significance calculated between male and female sex. Values are presented as the number of subjects (%). ART: antiretroviral therapy, CSB+: fortified Corn-Soy-Blend, BMI: body mass index, MUAC: mid-upper arm circumference, NA: not applicable, PLWHA: people living with HIV/AIDS.

After six months of supplementation, the nutritional status of the 125 participants and 24 pregnant and lactating women were assessed based on their BMI and MUAC, respectively. The nutritional status did not vary based on marital status, social class, or occupation. Undernutrition prevalence based on BMI reduced and was 24 (32.0%) for married and 8 (16.0%) for single (*P*=.0.523). According to Social classes, underweight were 12 (44.8%) for class 1, 18 (36.7%) for class 2 and 15 (31.3%) for class 3 (*P*=0.506).

According to the occupation, the underweight prevalence at sixth of supplements was insignificantly higher in people with other occupations 3 (60.0%) compared to farmers, 33 (35.5%) and those no jobs 9 (33.3%) (P=0.511). Based on MUAC, undernutrition prevalence were 14 (73.6%) for married and 2 (40.0%) in single (*P*=0.628). The details are in (Table 5).

Table 5. Nutritional status at the sixth month of supplementation

Variables	Nutritional status of PLWHA		P† value
	Normal	Underweight	
BMI at 6th month			
Marital status			
Married	51 (68.0)	24 (32.0)	0.523†
Single	42 (84.0)	8 (16.0)	
Social classes category			
Class 1	16 (55.2)	12 (44.8)	0.506†
Class 2	31 (63.3)	18 (36.7)	
Class 3	33 (68.7)	15 (31.3)	
Occupation			
Farmer	60 (64.5)	33 (35.5)	0.511†
No job	18 (66.7)	9 (33.3)	
Other	2 (40.0)	3 (60.0)	
MUAC at 6th month			
Marital status			
Married	5 (26.4)	14 (73.6)	0.628†
Single	3 (60.0)	2 (40.0)	
Social classes category			
Class 1	4 (66.6)	2 (33.3)	>0.999†
Class 2	9 (69.2)	4 (30.8)	
Class 3	2 (40.0)	3 (60.0)	
Occupation			
Farmer	4 (36.3)	7 (63.7)	
No job	8 (66.6)	4 (33.4)	0.778†
Other occupation	0 (0.0)	1 (100.0)	

Table 5: N, (%) and P-value (†) using Chi-square test,
BMI: body mass index, MUAC: mid-upper arm circumference, PLWHA: people living with HIV/AIDS

In general, based on BMI and MUAC, the nutritional status of the subjects reduced after ART initiation and improved significantly after six months of CSB^+ supplementation.
Mean BMI at the time of ART initiation in general subjects were 19.95 ± 1.51 kg/m^2 and decreased to 17.46 ± 0.55 kg/m^2 at CSB^+ initiation. At sixth month of CSB^+, mean BMI increased to 18.64 ± 0.53 kg/m^2. According to gender, Mean BMI at the time of ART initiation were 19.82 ± 1.30 kg/m^2 for male and 20.01 ± 1.71 kg/m^2 for female and decreased to 17.24 ± 0.53 kg/m^2 for male and 17.51 ± 0.53 $kg/m^2$for female at CSB^+ initiation and at the sixth month of CSB^+ supplement, mean BMI changed to 21.90 ± 2.44 $kg/m^2$for male and 18.62 ± 0.52 $kg/m^2$for female.

Based on MUAC, the mean changed from18.47 ± 0.45cm at CSB^+ initiation to 20.40 ± 0.53cm in the sixth month of supplements. Both mean BMI and MUAC increased significantly during six months of supplements (P <0.001 for BMI and P <0.001 for MUAC) (Table 6).

Table 6. Change in nutritional status with supplementation

Subject group	At the initiation of ART	At the initiation of CSB^+	At the 6^{th} month of CSB^+	$P^{\dagger}$ value
BMI, kg/m^2				
Total	19.95 ± 1.51 (16.8-25)	17.46 ± 0.55 (16-19)	18.64 ± 0.53 (17-21)	<0.001†
Male	19.82 ± 1.30 (17-23)	17.24 ± 0.53 (16-18.4)	21.90 ± 2.44 (17.4-19.5)	<0.001†
Female	20.01 ± 1.71 (15.8-25)	17.51±0.53 (16.5-18.5)	18.62 ± 0.52 (17.3-20.5)	<0.001†
MUAC, cm				
Pregnant &lactating women	NA	18.47 ± 0.45 (18-19)	20.40 ± 0.53 (20-21)	<0.001†

Mean ±SD, and †(P-value) using Anova test and T-test.

All values are presented as mean ±SD (range). BMI: body mass index, MUAC: mid-upper arm circumference, ART: antiretroviral therapy, CSB+: fortified Corn-Soy-Blend, SD: standard deviation, NA: not applicable.

The mean BMI trends in the general subject showed that at the initiation of ART, BMI was normal $\geq 18.5 kg/m^2$ and decreased as time went on. At the initiation of CSB^+, all participants had BMI$<18.5 kg/m^2$ and in the second month of supplements, BMI trends for single people already had restored to normal 19.9 kg/m^2. The BMI trended almost the same for the other factors. However, Trends in nutrition status improvement was higher in male compared to the female during six months of supplements. At the sixth month of supplementation, the mean BMI was $18.6 kg/m^2$ for the female while for male was 21.9 kg/m^2 (Figure 3).

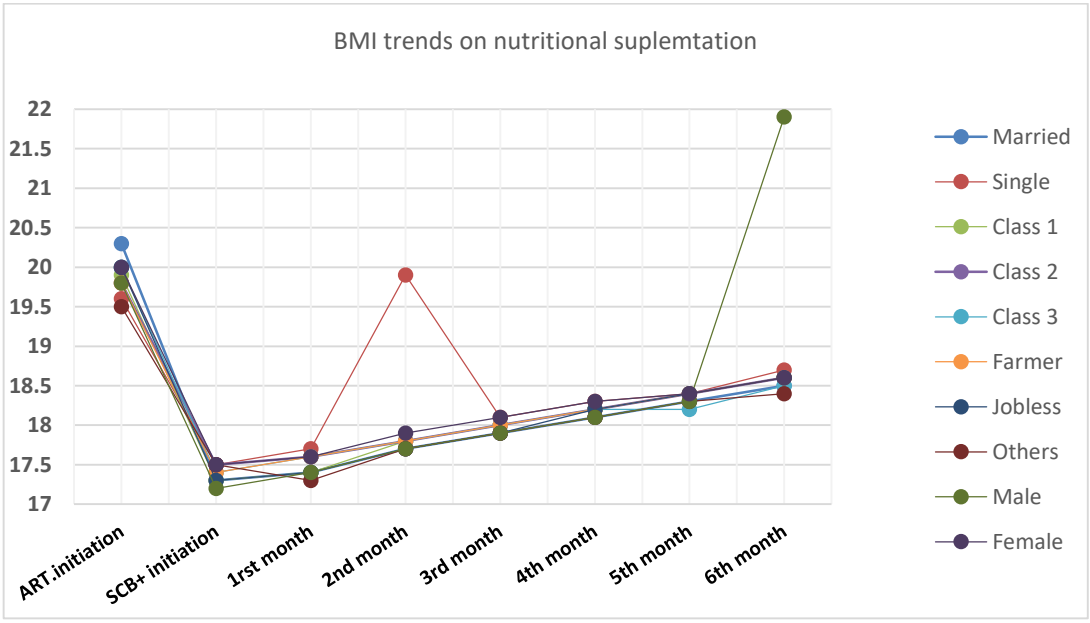

Figure 3. Mean BMI trend during six months of supplements of PLWHA

During the supplementation period, both BMI and MUAC trended positive. At the initiation of ART, the mean BMI was 19.96 kg/m^2 and decreased to17.46 kg/m^2 in general subjects. In the sixth month of supplements, BMI changed to 18.64 kg/m^2 while MUAC was 20.40 cm.

In the third month of supplementation, the mean BMI was 18.05 kg/m^2 and in the sixth month, the mean BMI was 18.64kg/m^2. Our study results showed that the minimum time required to restore normal BMI ≥18.5kg/m^2 was at least six months while the minimum time required to recover normal MUAC ≥21 cm for lactating and pregnant women was 8 months (Figure 4).

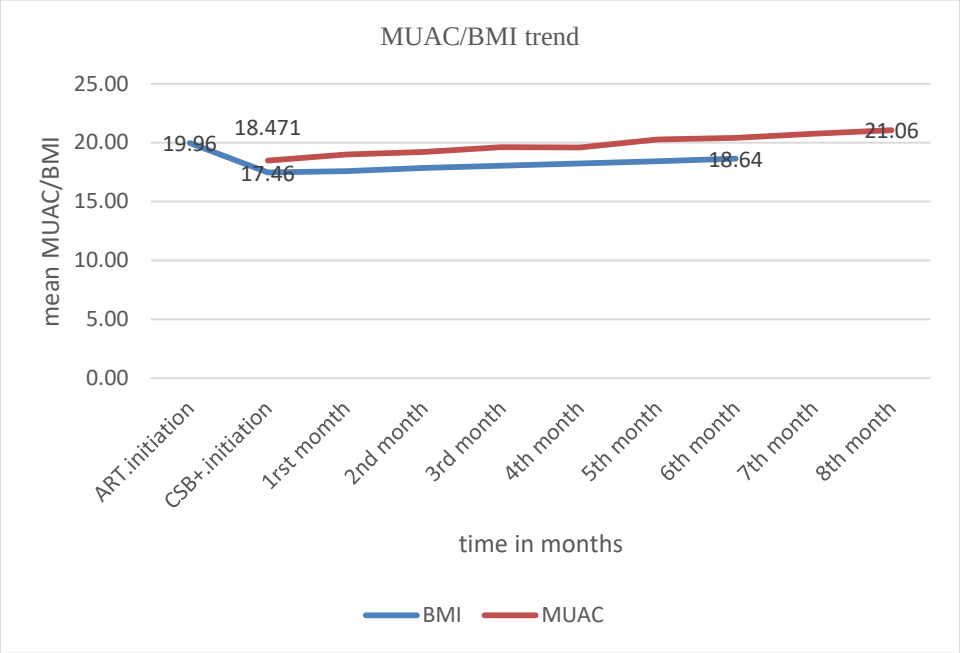

Figure 4: The minimum time required to restore normal nutrition status

5 Discussion

All 149 PLWHA in this study consumed 7.5 kg of CSB^+ per month per person with a serving size of 250 g/day as recommended by the National Nutrition Protocol guidelines [27]. In addition, all study participants lived in a rural area.

5.1 HIV/AIDS, Nutrition status and demographic factors

In this study of evaluating nutritional outcomes of HIV infected malnourished adults treated with CSB^+ in Rwanda, the study results of representative sample showed that the overall prevalence of undernutrition among PLWHA at the time of ART initiation was 12.8 % similar to the studies done in Brazil (7.3%), Zimbabwe (10%), Iran (11.1%), and Dilla Ethiopia (12.3%) [60].

Our findings showed the disparities of gender in the underweight of PLWHA. Among 149 PLWHA participated in the study, 64.4%were while the male was 35.6%. This may imply both the high HIV prevalence and undernutrition in females than in the male. The study conducted in 11 countries of sub-Sahara Africa about the nutrition status of women with HIV positive on ART has reported that 10.3% were underweight [61].

With the ART initiation, the mean weight of our subjects decreased from 53.31 ± 5.41 to 46.81 ± 4.48 kg, and the mean BMI decreased from 19.91 ± 1.56 to 17.44 ± 0.54 kg/m^2. It is known that the nutritional status of PLWHA is affected by progressive HIV before ART and by ART itself [62, 22]. Although effective and adherence to ART can improve the nutritional status of PLWHA, it was not possible to determine the treatment response to ART and adherence in this

study. It is also possible that some subjects might have had unfavorable ART responses at the time of initiation on supplementation.

Even though the social class did not affect the prevalence of underweight among PLWHA in this study, the prevalence was significantly influenced by the occupation of the subjects. The wasting syndrome was higher among people with other jobs compared to that in farmers and the unemployed. Interestingly, a study performed in Ethiopia showed that 12.3% of PLWHA had malnutrition due to unemployment and poverty [63].

5.2 CSB^+ Supplements and nutrition status improvement

CSB^+: Corn Soya Blend fortified flour and it is a mixture of nutrient-dense in protein, carbohydrates, vitamins, and minerals.

During six months of CSB^+ supplements, mean weight changed from 46.81±4.48 kg to 49.93 ± 4.28 kg and BMI increased from 17.44 ± 0.546 kg/m^2 at the time of CSB^+ initiation to 18.63 ± 0.535 kg/m^2 and MUAC changed from 18.47 ± 0.455 cm to 20.40 ± 0.532 cm. The current study findings showed that weight, BMI and MUAC within six months of supplementary feeding program significantly increased (*P*-value BMI<0.001, *P*-value MUAC<0.001).

Nutritional parameters, such as weight, BMI and MUAC, improved substantially during the six months of supplementary feeding programs. This shows that CSB+ improves the nutritional status of PLWHA in Rwanda, similar to that shown in studies of nutrition supplements in other countries and studies of CSB+ supplementation in PLWHA with wasting syndrome [49,54,45,25, 64].

However, some studies reported that CSB^+ supplements for moderate wasted PLWHA had limited effectiveness on improvements of nutrition status comparing to other supplements like peanuts or milk [65]. Other studies reported that nutritional recovery is enhanced by combining supplements with ART [55,66]. We are aware that interventions such as ART and treatment of opportunistic diseases might have influenced the overall nutritional status of the participants in this study, but were not accounted for as it was beyond the study's scope.

Based on sex, we found that BMI recovery with supplementation was higher in males compared to females (mean BMI of males changed from 17.24 ± 0.53 (kg/m^2) to 21.90 ± 2.44 (kg/m^2) and 17.51 ± 0.53 to 18.64 ± 0.52 (kg/m^2) for female at the sixth month of supplements. Females might be more vulnerable to malnutrition than males due to physiological events like pregnancy, breastfeeding and also over workloads. CSB+ reduced underweight prevalence by 64.0% in all subjects based on BMI and by 33.3% in lactating and pregnant women based on MUAC. The slow nutritional recovery in pregnant women could be attributed to physiological events such as pregnancy, childbirth, and breastfeeding.

In PLWHA, the energy requirements increase by 10% in the asymptomatic period and 20%-30% during the symptomatic period when compared to healthy individuals to maintain body weight and physical activities. With opportunistic infections such as tuberculosis (TB), the energy requirements increase by 50%-100% due to chronic lung disease, persistent diarrhea, AIDS progression, and an increase in resting energy expenditure [47,51,29]. Therefore, supplements rich in calories like CSB^+ and RUTF are critical for PLWHA.

5.3 Nutrition supplements and duration

The Rwanda National guidelines for nutrition care and support of underweight PLWHA recommend that supplements should be taken from three to six months to restore normal Weight, BMI or MUAC [29]. In our study findings, mean BMI in the third and sixth months of supplementation was 18.03 ± 0.46 kg/m^2 and 18.63 ± 0.535 kg/m^2 respectively, in line with the above guidelines.

However mean MUAC of pregnant and lactating women continued to be low both in the third and sixth months of supplements, 19.61 ± 0.53 cm and 20.40 ± 0.532cm respectively. Therefore, we may suggest based on study results that, at least six months are required for restoring normal nutritional status in PLWHA based on BMI, while this period may be prolonged in pregnant and lactating women with HIV/AIDS to at least eight months. Our study results are consistent with those of other studies that reported nutrition improvement was after sixth and twelfth months of supplementary feeding combined with nutrition education of PLWHA [67,55].

HIV/AIDS predisposes the affected individuals to malnutrition, thereby reducing their immunity and ability to fight opportunistic infections. As a consequence, household labor capacity is reduced, followed by food insecurity that further perpetuates undernutrition and affects the household access to appropriate nutritional care. With daily ART, it is essential to consume nutrient-dense foods to improve drug efficacy and the immune system. Supplement programs are vital for improving the nutritional status of PLWHA in resource-limited countries. The findings of this study are important for policymakers and improvements of the supplementary feeding program and for better nutrition results of wasted PLWHA.

5.4 Limitations of the study

The study did not consider the time difference between ART initiation and CSB initiation to identify how long it takes to get undernutrition for PLWHA. The study could not get information like the family size that may reflect food accessibility and sharing of PLWHA household, ART adherence and opportunistic infection of study's participants. In addition, the study did not assess food security and food safety of PLWHA' households and also our study had the limitation of missing data and none recorded participants with their anthropometrics.

5.5 Ethical Consideration

The research was approved by Yonsei University, Institutional Review Board of Severance Hospital (IRB No: Y-2019-0006). The patients' names and identification numbers were strictly kept confidential and not used for data collection.

6 Conclusion

HIV/AIDS leads to malnutrition in affected individuals and reduces their immunity and ability to fight opportunistic infections. As a consequence, household labor capacity is reduced, followed by food insecurity that leads to undernutrition. HIV/AIDS, therefore, limits the capacity of the affected households and individuals to access quality and appropriate healthy and nutritional care. With a daily intake of antiretroviral therapy, it is important to have nutrients density foods for drug efficacy and to improve the immune system to fight opportunistic infection. Food Supplements program is important to help to improve the nutrition status of PLWHA, especially in resources limited countries.

Nutritional supplementation with CSB^{+} improves the overall nutritional status in PLWHA with wasting syndrome, and at least six months of nutritional supplementation is required for BMI recovery and eight months for lactating and pregnant women to recover MUAC. Further studies must assess the food security and safety in households with PLWHA for early nutritional rehabilitation. We recommend special consideration to life events like pregnancy or lactating during supplementation programs to accurately determine nutritional needs and effectively measure outcomes.

7 List of Appendix

7.1 Data Collection Sheet used

Health Facility _____

Patient number (not tracnet) ----------

Date of data collection (DD/MM/YYYY) ----------

Quantity of Supplementary feeding per month ---------- kg

SECTION A: Demography

Age (Years) ----------

1 --

2 Sex: Male ☐ Female ☐

3 Marital status

- Married ☐
- Single ☐
- Divorced ☐
- Widow ☐

3 Profession (text) ----------

5 Social Class (1,2,3,4) ----------

SECTION B: HIV STATUS

1 Date of diagnosis (DD/MM/YYYY) ----------

2 HIV Type:

Type 1 Yes ☐ No ☐

Type 2 Yes ☐ No ☐

3 HIV Exposure category ☐

- Homosexual contact ☐
- Homosexual contact and injecting drug use ☐
- Injecting drug use only ☐
- Heterosexual contact ☐
- Heterosexual contact and injecting a drug ☐

Receipt of blood/products ☐

Perinatal Transmission ☐

SECTION C: IMMUNOLOGY and VIROLOGY STATUS

1 Date of blood collection (DD/MM/YYYY) ----------

2 CD4 Results ----------

3 CD8 Results ----------

4 HIV Viral load ----------

5 Total lymphocytes ----------

6 NCDs ----------

7 HIV related Disease diagnosed ----------

SECTION D: NUTRITIONAL STATUS

	Parameter	ART. Init.	CSB. Init.	1rst month	2nd month	3rd month	4th month	5th month	6th month
1	Weight (kg)								
2	Height (cm)								
3	BMI								
4	MUAC (CM)								
5	Viral Load								
6	CD4 count								

ART init Anti-retroviral therapy initiation. CSB init: Corn soya blend initiation

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